

Bear Hug: The Design and Development of an Active Deep Touch Pressure
Garment for Sensory Processing Disorder

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Dedication

This thesis is dedicated to my sister Jessica and nephew Gerard, whose appreciation of a warm hug from his auntie “Juli-li-lia” inspired this work.

Abstract

Many medical conditions, including sensory processing disorder (SPD), employ compression therapy as a form of treatment. SPD patients often wear weighted or elastic vests to produce compression, deep touch pressure (DTP), on the body, which have been shown to have a calming effect on the wearer. Unfortunately, current products (weighted vests and blankets, pneumatic garments, and negative ease stretch garments) are unable to meet their wearers' needs, in that they are unable to both provide the dynamic compression required, while also meeting the user's comfort needs by being unobtrusive. Recent advances in compression garment technology incorporate active materials to produce dynamic, low bulk compression garments that can be remotely controlled. The purpose of this thesis is twofold, first, to identify requirements for a DTP therapy garment, and second, to build a dynamic garment for DTP therapy.

A literature review, a qualitative investigation with experts and occupational therapists, and a quantitative study of current DTP garments were used to build a problem variable framework for a more optimal DTP therapy garment. The variables that were identified fell into two major categories; system variables, which encompass the basic important features needed in order to provide DTP on the body, and usability variables, which are the other important features required for an effective and efficient system. Following this investigation, an active compression vest using shape memory alloy (SMA) spring actuators was developed in order to better meet these requirements than existing DTP products.

The vest prototype incorporates 16 SMA spring actuators (1.25 mm diameter, spring index = 3) that constrict when heated, producing large forces and displacements that can be controlled via an applied current. When power is applied (up to 43.8 W), the prototype vest generates increasing magnitudes of pressure (up to 37.6 mmHg, spatially averaged across the front of the torso) on a representative child-sized form. Average pressure generated was measured up to 71.6% of the modeled pressure, and spatial pressure non-uniformities were observed that can be traced to specific garment architectural features.

Although there are no consistent standards in magnitude of applied force in compression therapy garments, it is clear from comparative benchmarks that the compression produced by this garment exceeds the demands of the target application. Additionally, the garment can produce a dynamic and controllable pressure durations and magnitudes within a low and unobtrusive form factor, which are identified as important requirements for DTP therapy. There are several variables that require further investigation, including thermal comfort of the garment. This study demonstrates the viability of SMA-based compression garments as an enabling technology for individualized and enhanced SPD (and other compression-based) treatment. Additionally, the technology can be used as a tool to determine and standardize optimal treatment parameters.

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CHAPTER 1. INTRODUCTION

1.1 Problem Statement

Sensory Processing Disorder (SPD), previously known as Sensory Integration Dysfunction (SID), manifests when the central nervous system (CNS) has difficulty receiving and processing sensory signals and providing the appropriate motor or behavioral response (About SPD, 2017). This can lead to problems such as motor clumsiness, behavioral problems, anxiety, depression, school failure, and challenges performing many everyday tasks (About SPD, 2017). Some individuals with SPD can self-regulate with the help of deep touch pressure (DTP) compression therapy. There are two significant deficiencies with current DTP practices. First it is not clear what the ideal treatment parameters (e.g. duration, location and magnitude of pressure etc.) should be; and second that in spite of that fact, there are some established best practices, but the products on the market seem to fall far short of those best practices. This thesis aims to accomplish three things: examine the requirements, based on qualitative and quantitative assessments of current practices; develop a prototype that exceeds performance of current commercial alternatives; and enable future, rigorous, and quantitative studies to better determine optimum treatment strategies.

1.2 Significance

SPD is estimated to affect 5%-16% of all children (Ahn, Miller, Milberger, & McIntosh, 2004) (Ben-Sasson, Carter, & Briggs-Gowan, 2009). Problems in the development, information processing, and behavior of the individual affected can be produced when the input from one or more of the senses is not integrated appropriately in the brain (Haar,

1998). Those with SPD can become overwhelmed by the sensory signals around them, making it difficult to function and creating extreme anxiety (Ayres J. A., 1972) (Haar, 1998). This can be debilitating and impede the individual from functioning in their daily life (Grandin, 1992).

SPD appears on its own or can manifest in conjunction with autism spectrum disorder (ASD) (a neurodevelopmental disorder that impairs the individual's ability to communicate and interact with others (Mayo Clinic, 2014) or with attention deficit and hyperactivity disorder (ADHD) (a chronic condition that includes a combination of persistent problems such as difficulty sustaining attention, hyperactivity and impulsive behavior (Mayo Clinic, 2016) (Grandin, 1992) (Vandenberg, 2001) (Brout, n.d.). It has been suggested that at least 75% of children with ASD have significant symptoms of SPD (Brout, n.d.).

1.3 Current Treatment Deficiencies

DTP products on the market, which encompass non-wearable treatments as well as weighted, stretch, and pneumatic garments, have several different shortcomings. Non-wearable options (Krauss, 1987); (Grandin, 1992); (Edelson, Edelson, Kerr, & Grandin, 1999); (Chen, Yang, Chi, & Chen, 2013) are large and stationary preventing user mobility and need based use. Of the wearable options, only the pneumatic garments are capable of dynamic compression (Iggo & Muir, 1969), which can help prevent acclimation to pressure among other benefits. However, the pneumatic garments require inflation with a pump in order create compression, which can draw unwanted attention to the wearer. The stretch garments are low-profile, making them unobtrusive, however they

are non-dynamic and difficult to don and doff. The weighted garments must also be doffed or have weights removed to alleviate pressure. They also limit user mobility as they are not meant to be worn during activities due to potential user injury (Olson & Moulton, 2004). A mobile, dynamically controllable garment with a low-profile form factor is needed.

1.4 Research Objectives

The aim of this thesis is threefold. The first objective is to determine DTP garment requirements for the treatment of SPD. This is accomplished through a review of the literature as well as through both qualitative interviews with occupational therapists and experts and quantitative spatial pressure sensing of existing DTP standard products. The second aim is to build a system that meets the requirements developed in the first objective, including dynamic compression and an unobtrusive form factor. A garment was built using shape memory alloy (SMA) springs that contract when heated to create a children's deep pressure vest that can constrict on command, while being simultaneously low profile and adjustable. The garment can be controlled via wireless remote, allowing wearer self-adjustment and enabling the child's parent, guardian, or occupational therapist (OT) to give a comforting "hug" potentially from anywhere in the world. Third, this garment can then enable future research into optimal treatment parameters for DTP therapy.

1.5 Thesis Structure and Key Findings

The chapters of this thesis are organized as follows: Chapter II covers a literature review of important theories and related studies and a discussion of DTP treatment methods and

protocols. It becomes clear that there is inconsistency in treatment and research methodologies for DTP therapies. Important requirements are identified and current product deficiencies become clear. Shape memory alloy activated compression garments are recognized as a dynamic, controllable, and form fitting alternative to current DTP products. Chapter III covers a qualitative and quantitative investigation of the requirements for DTP therapy treatment. Interviews with occupational therapists and experts and an evaluation of the pressure distribution of current DTP therapy products are conducted. The chapter culminates in a proposed requirement framework for DTP therapy garments that incorporating both system and usability requirements. Current DTP products are evaluated using the framework and found to be deficient. Chapter IV, covers the technology development and evaluation of the new active compression garment build to meet the needs outlined in the Chapter III framework. The garment meets more requirements than existing DTP products, namely repeatable, controllable and dynamic compression in an unobtrusive form factor. However, future work should be done so that all requirements can be met. Chapter V covers the conclusions, limitations and future work for this thesis.

1.6 Key Terms

- **Autism spectrum disorder (ASD)** – A neurodevelopmental disorder that impairs the individual's ability to communicate and interact with others (Mayo Clinic, 2014).
- **Attention deficit and hyperactivity disorder (ADHD)** - A chronic condition that includes a combination of persistent problems such as difficulty sustaining

attention, hyperactivity and impulsive behavior (Mayo Clinic, 2016).

- **Occupational therapy** - A form of therapy for those recuperating from physical or mental illness that encourages rehabilitation through the performance of activities required in daily life.
- **Sensory processing / sensory integration** – The mechanism with which individuals experience, interpret, and respond to different stimuli in their environment (Ayres & Robbins, Sensory integration and the child: Understanding hidden sensory challenges, 2005)
- **Sensory processing disorder (SPD) / Sensory integration dysfunction (SID)** – “A developmental disorder defined by deficits in the central processing of vestibular, proprioceptive, and tactile sensory inputs, that are not attributable to either peripheral or cortical central nervous system dysfunction” (Fisher & Murray, 1991 as cited in (Haar, 1998)).
- **Sensory modulation disorder (SMD)** – a pattern of SPD, where individuals have difficulty regulating their responses to sensory stimuli. This encompasses sensory over-responsiveness, sensory under-responsiveness and sensory craving (About SPD, 2017)
- **Sensory-based motor disorder (SBMD)** – a pattern of SPD, where individuals have difficulty with their balance, motor coordination and the performance of skilled, non-habitual and/or habitual motor tasks (About SPD, 2017)
- **Sensory discrimination disorder (SDD)** - a pattern of SPD, where individuals have difficulty interpreting subtle qualities of objects, places, people or other

environments (About SPD, 2017)

- **Tactile defensiveness** - “A sensory integrative dysfunction in which tactile sensations cause excessive emotional reactions, hyperactivity, or other behavior problems” (Ayres & Robbins, Sensory integration and the child: Understanding hidden sensory challenges, 2005)
- **Deep touch pressure (DTP)** – “The type of surface pressure that is exerted in most types of firm touching, holding, stroking, petting or animals, or swaddling” (Grandin, 1992)
- **Light touch pressure (LTP)** – “A more superficial stimulation of the skin, such as tickling, very light touch, or moving hairs on the skin” (Grandin, 1992)
- **Shape memory alloys (SMAs)** - A metal alloy that can recover from apparent permanent strains when heated above a certain temperature
- **Sensory integration intervention (Ayres, 1972) / Ayres Sensory Integration ® (ASI)** - “A play-based method that uses active engagement in sensory-rich activities to elicit the child’s adaptive responses and improve the child’s ability to successfully perform and meet environmental challenges” (Watling & Hauer, 2015). “Treatment involving sensory stimulation and adaptive responses to it according to the child’s neurologic needs. Therapy usually involves full body movements that provide vestibular, proprioceptive, and tactile stimulation” (Ayres & Robbins, Sensory integration and the child: Understanding hidden sensory challenges, 2005)
- **Sensory based integration (SBI)** - “Occur in the child’s natural environment and

consist of applying adult-directed sensory modalities to the child with the aim of producing a short-term effect on self-regulation, attention, or behavioral organization” (Watling et al., 2011)

- **Sensory diet** – A combination of sensory input treatments, such as weighted vests, brushing, bouncing on a ball, and adapted seating devices that allow motion that are either provided in a systematic manner throughout the child’s day or as needed in response to the child’s self-regulation (Watling & Hauer, 2015)
- **Parasympathetic nervous system** – “The parasympathetic nervous system is one of three divisions of the autonomic nervous system. Sometimes called the rest and digest system, the parasympathetic system conserves energy as it slows the heart rate, increases intestinal and gland activity, and relaxes sphincter muscles in the gastrointestinal tract.” (Reference terms: Parasympathetic nervous system, n.d.)
- **Modulation** – “the ability to monitor and regulate information in the interest of generating an appropriate response to particular stimuli” (Dunn, 1997)
- **Habituation** – “the simplest form of learning in the CNS and occurs when the nerve cells and CNS systems recognize the stimulus as familiar and decrease transmission among the cells because there is not a perceived need to continue to respond to the stimulus” (Dunn, 1997)
- **Sensitization** – during sensitization, the “CNS recognizes the stimulus as important or potentially harmful and generates a heightened response” (Dunn, (Dunn, 1997)
- **Poor registration** – “When young children have difficulty registering stimuli due

to high neurological thresholds and act in accordance with those thresholds, they tend to have a dull or uninterested appearance” (Dunn, 1997)

- **Sensitivity to Stimuli** – “Young children who are sensitive to stimuli due to low thresholds and who act in accordance with those thresholds tend to be hyperactive or distractible” (Dunn, 1997)
- **Sensation Seeking** – “When young children have high thresholds but develop responses to counteract their thresholds, they may engage in behaviors to increase their sensory experiences” (Dunn, 1997)
- **Sensation avoiding** – “When young children have low thresholds and develop responses to counteract their thresholds, they try to avoid activating their thresholds; they might appear to be resistant and unwilling to participate” (Dunn, 1997)
- **Clo** – A measure of the thermal insulation of a garment ensemble (Watkins & Dunne, 2015)

CHAPTER 2. BACKGROUND

This chapter introduces the different theories surrounding sensory integration and sensory processing disorder (SPD). Next, the different treatment methods for SPD, including deep touch pressure (DTP) therapy are examined. This is followed by a review and discussion of the literature surrounding the different DTP treatment methods and protocols, findings, and gaps. The chapter ends with the objectives of this thesis, which are: (1) to determine the requirements for DTP treatments for SPD, and (2) to build a DTP garment that meets these requirements.

2.1 Key Theories

Theories, key terms and definitions are evolving in this field of occupational therapy, which can lead to some confusion (Watling & Hauer, 2015). Even the term sensory processing disorder (SPD) was originally known as sensory integration dysfunction (SID). There are three key theories that have contributed to this field of research. By discussing the contributions of each some of the confusion can be dispelled. These theories include, Ayres Sensory Integration Theory (Ayres J. A., 1972), the sensory processing model, used to help understand different sensory profiles (Dunn, 1997), and a model of the different types of sensory processing disorder (Miller LJ et al., 2012).

2.1.1 Ayres Sensory Integration Theory

The theory of Sensory Integration, Ayres Sensory Intregation ® (ASI), was initially developed by A. Jean Ayres in the 1960s and 70s (Parham & Mailloux, 2009). Sensory integration, now also known as sensory processing, is the mechanism with which individuals experience, interpret, and respond to different stimuli in their environment (Ayres J. A., 1972). Sensory integration is hypothesized to be partly responsible for development of perception, language, cognition, academic skills, emotional maturation, behavior control, coping with stress, moving without fear, the ability to move and be touched without aversiveness, as well as academic skills, self-care and self-management (Haar, 1998). Without the ability to accurately process relevant information, modulate and regulate incoming stimuli and integrate information from all sensory systems to carry

out functional reactions and activities, individuals are unable to function adaptively (Parham and Mailloux, 2009).

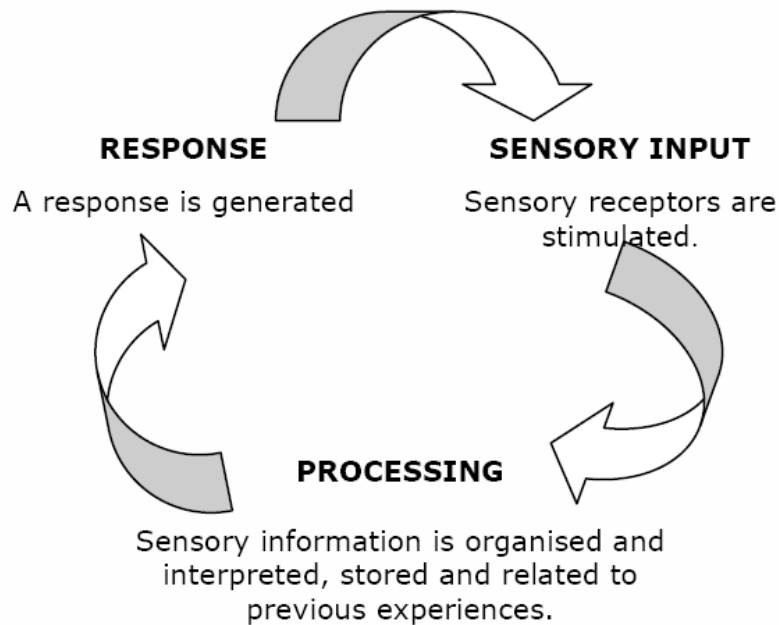


Figure 1: Sensory Processing Model

(Sensational Kids Occupational Therapy, n.d.)

ASI was developed in order to explain the observed relationship between (1) difficulties in the interpretation of information from the body and environment, and (2) deficits in academic or neuromotor learning (Fisher & Murray, 1991). ASI hypothesizes that learning is dependent on the ability of normal individuals to take in sensory information from their environment and the movement of their own bodies. The individuals then process and integrate these inputs in the central nervous system. They are then able to use this sensory information to plan and organize their behavior (Ayres & Robbins, Sensory

integration and the child: Understanding hidden sensory challenges, 2005) ; (Fisher & Murry, 1991). There are five assumptions of ASI. These include (1) neural plasticity, (2) developmental sequence, (3) nervous system hierarchy, (4) adaptive behavior, and (5) inner drive (Fisher and Murray, 1991).

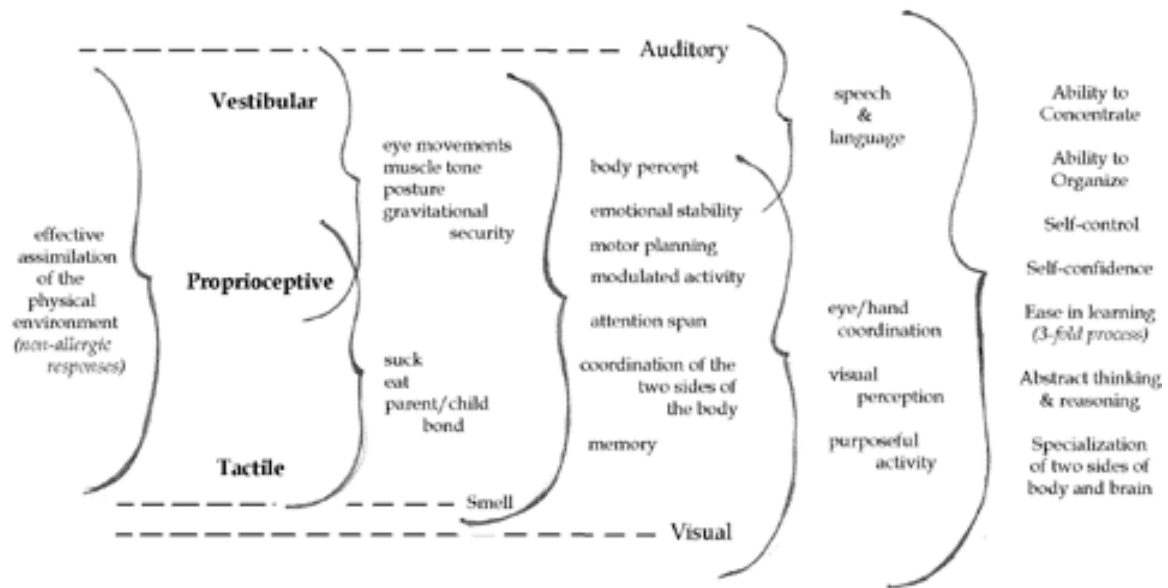


Figure 2: Sensory Integration Model.

(Ayres & Robbins, Sensory integration and the child: Understanding hidden sensory challenges, 2005)

Typically, an individual's brain and central nervous system (CNS) habituate (or adapt), to stimuli. This process of modulation, also known as regulation, happens automatically and reacts as needed dependent on the situation. When someone cannot habituate to a stimulus, they experience discomfort, known as sensory integration dysfunction (Parham and Mailloux, 2009).

2.1.2 Sensory Processing Profiles

Winifred (Winnie) Dunne added to Aryes work by developing a model that helps to determine sensory profiles for children in order to more fully understand their behavior and develop methods to help them overcome difficulties. The model envisions the relationship between neuroscience and behavioral concepts and helps visualize the different sensory sensitivities and behaviors of children (Dunn, 1997). The neurological component, shown in the vertical axis of the model, indicates the “amount of stimuli needed for the nervous system to notice or react to stimuli” (Dunn, 1997). The behavioral response, the horizontal axis, indicates “the manner in which the young child responds in relation to the thresholds” (Dunn, 1997). Children can fall anywhere on the continuums of each axis and where they are can change depending on the day. For instance, it might change if they are more tired (Dunn, 1997).

Neurological Threshold Continuum	Behavioral Response Continuum	
	responds in ACCORDANCE with threshold	responds to COUNTERACT the threshold
HIGH (habituation)	Poor Registration	Sensation Seeking L.
LOW (sensitization)	Sensitivity to Stimuli	Sensation Avoiding

Figure 3: Winifred Dunn's Sensory Profile Model showing the relationships between behavioral responses and neurological thresholds.

(Dunn, 1997)

Lucy Jane Miller coined the term Sensory Processing Disorder (SPD), and developed a model that explains the different types of SPD. There are three different patterns of SPD (Lane, Miller, & Hanft, 2000)

- Pattern 1: Sensory Modulation Disorder
- Pattern 2: Sensory-Based Motor Disorder
- Pattern 3: Sensory Discrimination Disorder

The different types are outlined in Miller's model in Figure 4: Sensory Processing Disorder Model.

Pattern 1, or Sensory Modulation Disorder (SMD) is the “difficulty of regulating

responses to sensory stimuli.” There are several different types. These are Sensory Over-Responsive, which is the “predisposition to respond too much, too soon, or for too long to sensory stimuli most people find quite tolerable.” The second sub-type of SMD is Sensory Under-Responsive, or the “predisposition to be unaware of sensory stimuli, to have a delay before responding, responses are muted or responds with less intensity compared to the average person.” The third sub-type of SMD is Sensory Craving, which is when one is “driven to obtain sensory stimulation, but getting the stimulation results in disorganization and does not satisfy the drive for more” (About SPD, 2017; Lane, Miller, & Hanft, 2000). Those with SMD, particularly sensory over-responsive individuals, as well as some with Sensory Discrimination Disorder will be most benefitted by Deep Touch Pressure therapy, the focus of this thesis work.

Pattern 2, or Sensory-Based Motor Disorder (SBMD) is when individuals have “difficulty with balance, motor coordination, and the performance of skilled, non-habitual and/or habitual motor tasks.” There are two types, Postural Disorder and Dyspraxia. Postural Disorder is when those affected have an “impaired perception of position of body position; poorly developed movement patterns that depend on core stability. Thus, appears weak and/or has poor endurance.” Dyspraxia is the “difficulty thinking of, planning and/or executing skilled movements especially novel movement patterns” (About SPD, 2017; Lane, Miller, & Hanft, 2000). Compression therapy can also be beneficial for these components of SPD by helping to support and strengthen the core. However, this is not the focus of this thesis research.

The third pattern, Sensory Discrimination Disorder (DD), is the “difficulty

interpreting subtle qualities of objects, places, people or other environments.” There are several different sub-components encompassing auditory, visual, tactile, vestibular, proprioceptive, gustatory, olfactory, and interception stimuli. Two, tactile and proprioceptive may also benefit from DTP therapy. Tactile DD is the “difficulty determining / interpreting characteristics of stimuli that is felt on the skin or interpreting higher level visual/spatial characteristics of touch (includes stereognosis and graphesthesia disorders).” And the proprioceptive component involves “difficulty determining/interpreting characteristics of sensory stimuli through use of the muscles and joints” (About SPD, 2017; Lane, Miller, & Hanft, 2000).

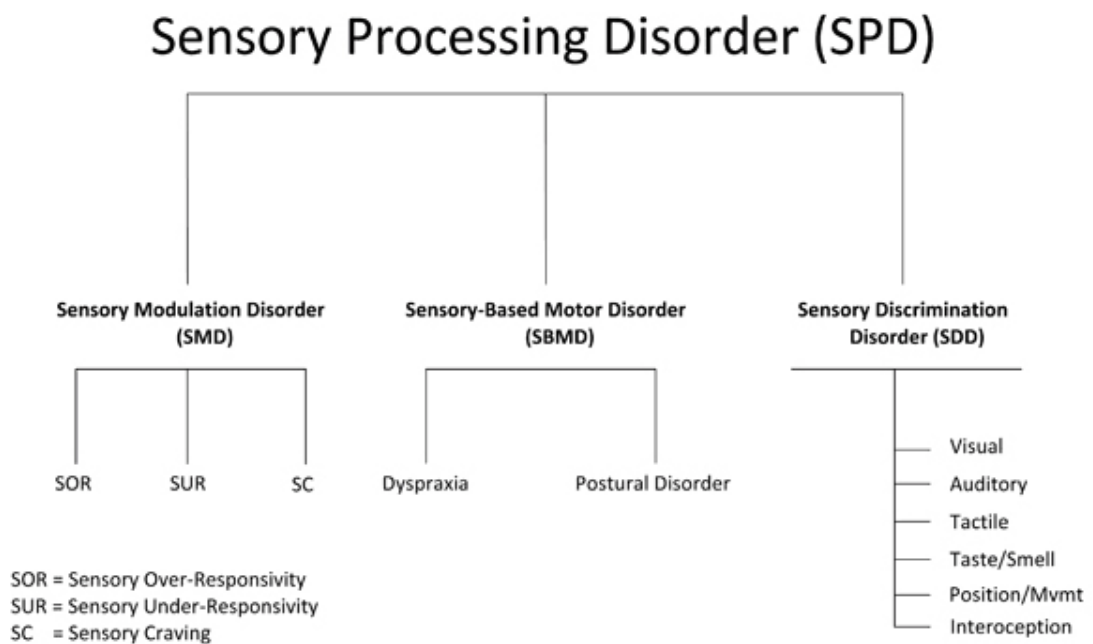


Figure 4: Sensory Processing Disorder Model.

(Lane, Miller, & Hanft, 2000)

2.2 Treating SPD

There are multiple methods for treating SPD that occupational therapists use in

practice. It has been noted that there is an extreme amount of confusion in the definitions, theories and expected outcomes for SPD treatments (Watling & Hauer, 2015). There have been recent movements to clarify and define these different theories and practices (Watling & Hauer, 2015). Watling and Hauer describe the differences between Ayres Sensory Integration ® (ASI) and sensory-based integration (SBIs), which are often confused with one another. Watling and Hauer describe ASI as “a play-based method that uses active engagement in sensory-rich activities to elicit the child’s adaptive responses and improve the child’s ability to successfully perform and meet environmental challenges” (Watling & Hauer, 2015).

The Fidelity Measure is a method used to distinguish SBIs and ASI. There are 10 essential elements that are used to classify interventions as ASI using a 5-point scale (Parham, et al., 2011). These elements are: (1) Ensuring physical safety, (2) presenting a range of sensory opportunities, (3) helping the child to attain and maintain appropriate levels of alertness, (4) challenging postural, ocular, oral, or bilateral motor control, (5) challenging praxis and organization of behavior, (6) collaborating with the child on activity choices, (7) tailoring activities to present the just-right challenge, (8) ensuring that activities are successful, (9) supporting the child’s intrinsic motivation to play, and (10) establishing a therapeutic alliance with the child (Parham, Cohn, Spitzer, & Koomar, 2007). The second element, presenting a range of sensory opportunities, includes compression therapy as a form of tactile sensory input.

In contrast, SBIs “occur in the child’s natural environment and consist of applying adult-directed sensory modalities to the child with the aim of producing a short-term

effect on self-regulation, attention, or behavioral organization” (Watling & Hauer, 2015).

SBIs include weighted vests, brushing, bouncing on a ball, and adapted seating devices that allow motion. These SBIs are provided when needed in response to the child’s self-regulation, and are applied systematically throughout the day. These activities can be combined into a “sensory diet” (Watling & Hauer, 2015).

2.3 Sensory Over-Responsivity (SOR) and Anxiety

Ayres and Tickle noted that sensory integration therapy was more effective for individuals on the autism spectrum with normal or over-aroused sensory responsiveness, rather than those who were under-aroused (Ayres & Tickle, 1980). Green and Ben-Sasson explored different theories that explain the possible causal relationships between anxiety disorders and sensory over-responsivity (SOR), for children on the autism spectrum (Green & Ben-Sasson, 2010).

One of the proposed models, the Primary SOR Model operates under the assumption that SOR has a causal relationship with anxiety. Individuals with SOR can develop a specific phobia when they encounter sensory stimuli along with an object, such as loud noises from balloons popping, and through classic conditioning associating the two. However, individuals can also develop generalized anxiety when stimuli are not associated with a specific object, but a place or event. For instance, children may avoid birthday parties in general, etc. Sensory stimulation (SS) therapy can be conceptualized under the SOR model, as seen in Figure 5: Primary Sensory Over-Responsivity (SOR) Model. The sensory stimulation (SS) intervention, for example compression therapy or deep touch pressure (DTP), can help the child regulate his or her arousal level by

influencing the nervous system, leading to a reduction in generalized anxiety (Green & Ben-Sasson, 2010).

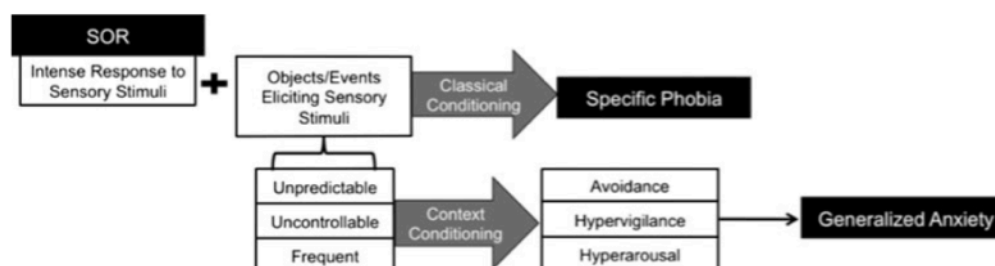


Figure 5: Primary Sensory Over-Responsivity (SOR) Model

(Green & Ben-Sasson, 2010).

2.4 Deep Touch Pressure (DTP) Therapy

Deep touch pressure (DTP) is one of the SS treatments used to help those with SPD (Morrison, 2007). OTs recommend the use of compression products to treat SPD (Olson and Moulton, 2004), and some individuals with SPD seek out deep touch pressure to help process sensory signals (Grandin, 1992). DTP is a type of tactile sensory input that can be produced when firmly touching, stroking, squeezing, holding, hugging or swaddling, etc. (Grandin, 1992). DTP therapeutic interventions modulate the physiological and psychological statuses through proprioceptive input from the central nervous system and by calming the individual (Krauss, 1987). The deep pressure proprioception provided through compression therapy is argued to promote the production of neurotransmitters (serotonin and dopamine) that can provide a calming input to the central nervous system (Morrison, 2007). DTP helps to increase activity in the parasympathetic division of the autonomic nervous system (ANS) and decrease activity in the sympathetic division

(Chen, Yang, Chi, & Chen, 2013). The sympathetic division activates what is known as the “fight or flight” response, this part of the nervous system accelerates the heart rate and raises the blood pressure. The parasympathetic division is known as the rest and digest system. It conserves energy, slows the heart rate, and increases gland activity (Reference terms: Parasympathetic nervous system, n.d.) By reducing the flight and flight response, and activating the resting state, anxiety can be reduced and the individual can be calmed.

2.5 Studies Evaluating DTP

Various studies evaluate the effectiveness of DTP therapy as a treatment. There are multiple products, some wearable and some non-wearable, that can be used to apply DTP. Some found positive results when using DTP as an intervention, while others found non-significant results. This section explores the different practices and findings from these studies, and is organized by DTP treatment product, starting with non-wearable options, followed by wearable options.

2.5.1 Non-Wearable DTP

There are several different modalities for applying DTP to the body. Studies have evaluated the effectiveness of some of the non-wearable DTP options including a “Squeeze Machine” developed by Temple Grandin (Grandin, 1992); (Edelson, Edelson, Kerr, & Grandin, 1999)), a pneumatic apparatus called the “Hug’m” machine (Krauss, 1987), and weighted blankets (Chen, Yang, Chi, & Chen, 2013). Both positive (Chen et al., 2012; Grandin, 1992; Edelson et al., 1999) and non-significant (Krauss, 1987) results

for non-wearable DTP interventions are found. The results suggest that slowly changing pressure and constant pressure are more relaxing than quickly pulsating pressure (Grandin, 1992). It is also suggested that individuals with high initial arousal or anxiety may benefit more from the calming effect of DTP therapy (Edelson et al., 1999; Krauss, 1987), and that self-determined, rather than scheduled times may be more appropriate for DTP therapy (Edelson, Edelson, Kerr, & Grandin, 1999). Additionally, DTP therapy may not be appropriate for everyone and the magnitude and location of preferred pressure may change per person (Krauss, 1987). Limitations of these studies are that they use different methodologies, populations, and desired outcomes.

2.5.1.a Grandin's Squeeze Machine

Grandin developed and tested the effectiveness of a DTP machine called the Squeeze Machine. This machine was composed of two foam pads to apply lateral pressure to both sides of the body. According to the study, the air pressure on the 5cm diameter air cylinder is set at 60psi for adults, “which allows up to 43kg(95lbs.) of pressure to be exerted on each rope attached to the sides” and for children under the ages of 8-9, “the pressure is set at 30-40psi” (Grandin, 1992). The exact magnitude of pressure applied to the body is unclear due to unknowns in the distribution of the force applied to the body.

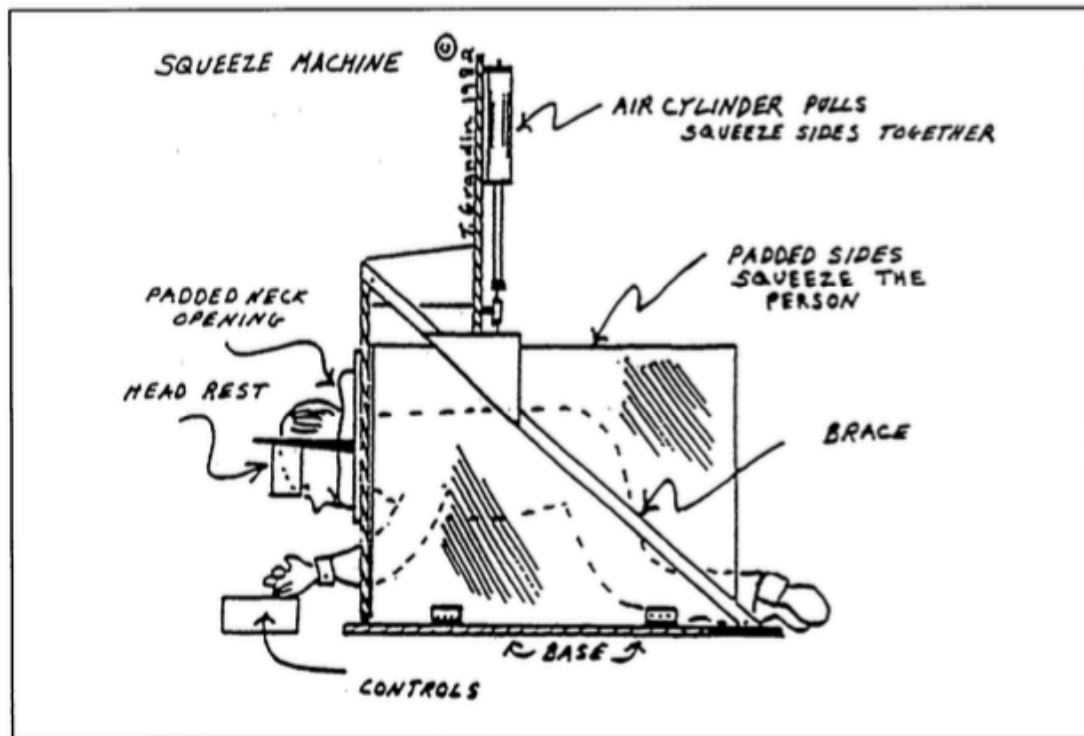


Figure 1. Grandin's Hug Machine. Note. Copyright 1982 by Temple Grandin. Reprinted with permission.

Figure 6: Grandin's Squeeze Machine

(Edelson, Edelson, Kerr, & Grandin, 1999)

Grandin conducted a study using the squeeze machine at different settings to determine the calming effects of DTP for ($n=40$) college students, ages 18-25. The participants did not know the purpose of the Squeeze Machine, but were told it was part of a sensory perception experiment (1992). The machine was operated in three different modalities. These were constant, quick pulsation (50 cycles per minutes), and slow pulsation (15 cycles per minute). The participants received each mode for 5 minutes in random order and were then asked to rate their relaxation from 1 (almost asleep) to 10 (very excited). Grandin used Duncan's multiple range test with $\alpha = 0.05$ for her statistical

analysis. The results indicated that the stationary mode and slow modulation were statistically different from fast pulsation and were found to be more relaxing (Grandin, 1992). Grandin's work suggests that slowly changing pressure and constant pressure are more relaxing than quickly pulsating pressure. However, the participants were regular college students, so it is unclear if this applies to treatments for those with SPD.

Edelson et al. found positive results when expanding on Grandin's study (1999) with a pilot study evaluating the effects of deep pressure, using Grandin's machine, on anxiety level and arousal reduction for twelve children, ages 4-13, diagnosed with autism (1999). The participants were randomly assigned to either an experimental group that received deep pressure, or placebo group that were situated in the disengaged squeeze machine without pressure applied. Both experimental and placebo groups received two twenty-minute sessions a week for six weeks. Arousal level was measured both behaviorally, using the Conner's Parent Rating scale, and physiologically, using galvanic skin response (GSR). Behavioral results show a significant reduction on the tension scale and marginally significant reduction on the anxiety scale for the participants who received deep pressure compared to those who received the placebo. Results for the GSR arousal for participants in the deep pressure groups show that participants with somewhat higher initial GSR measures on average had a decrease in GSR after the treatment. No adverse side effects from deep pressure were found (Edelson, Edelson, Kerr, & Grandin, 1999). Findings suggest that DTP may have a calming effect for persons with ASD, especially for those with high initial arousal.

Limitations of the Edelson et al. study were the small sample size and that the

sample, children diagnosed with autism, were unable to personally communicate the deep pressure's effect on their anxiety or arousal (1999). Another limitation of the sample was that it was difficult to recruit children all with high initial anxiety levels. A methodological limitation was that the therapy treatments were arbitrarily scheduled, due to the limited accessibility of the machine, rather than having the Squeeze Machine available for the children when they had higher anxiety levels. Edelson et al. suggest that self-determined times may be more appropriate for deep pressure use rather than scheduled times (1999). Another methodological limitation is that the act of collecting GSR data itself may have increased anxiety level for the participants, making it more difficult to distinguish physiological changes due to deep pressure (Edelson, Edelson, Kerr, & Grandin, 1999).

A key takeaway from this non-wearable study is that a context aware and wearable system may be necessary in order to provide optimal treatment for SPD. Edelson et al. found that children with autism may not be able to communicate the treatment's effectiveness (Edelson, Edelson, Kerr, & Grandin, 1999). Alternative measures should be taken in order to determine if the treatment is working. These could include sensors that detect the child's anxiety level. Additionally, DTP treatment may be more effective at reducing anxiety if the participants have a higher initial anxiety level, so it would be better to apply the treatments when anxiety levels are higher rather than at scheduled times. Non-wearable systems make this more difficult to do this because they are less mobile. Additionally, an integrated anxiety sensor for a context aware system could be beneficial for detecting need as well as effectiveness. This system, if controllable, could

travel with the wearer and respond when needed while also tracking treatment outcomes.

2.5.1.b Hug'm apparatus

In another study, a pneumatic DTP machine, the “Hug'm” apparatus, was used to determine the effects of DTP on anxiety for people without SPD (Krauss, 1987). Krauss investigated the effects of DTP on objective and subjective anxiety with 23 college students (separated into two groups, one with high and one with low trait anxiety) by comparing when pressure was applied and when participants were in the apparatus without pressure applied (1987). Subjective anxiety was measured using the physiological measure of heart rate and objective anxiety was measured using the self-reported State Trait Anxiety Indicator (STAI). Anxiety as a personality trait was also measured using the STAI questionnaire. Participants were randomly selected from the high and low trait anxiety groups to participate in the study.

The Hug'm apparatus, used to apply circumferential DTP, was constructed with two stacked air mattresses resting on a stationary mattress and connected with a rope and pulley system (Krauss, 1987). The apparatus applied DTP to the body surface between the mid-chest and the calves. The amount of pressure was chosen by what was “most comfortable” for the participants. The pressure was applied for 15 minutes. Paired *t* tests, with a *p* value of $\leq .05$ and a 2 X 2 ANOVA were used to evaluate the machine (Krauss, 1987).

The results were not significant. The application of DTP enhanced subjective relaxation more than the control, but there was not a significant change in objective (heart rate) or subjective (state) anxiety levels between control and experimental groups

(Krauss, 1987).

These findings could be due to multiple different variables. Krauss speculated that the results of the study might in part be due to low initial levels of anxiety in the participants (1987). Krauss also noted that DTP might not be an effective calming technique for everyone, and postulates these differences may be due to the treatment technique, the manner in which it is administered, the patient, or a confounding interpersonal variable between the therapist and the patient (Krauss, 1987). Krauss also indicated that location and amount of pressure could have influenced participants' response to DTP. Some participants who felt more pressure on their thighs would have preferred to have additional pressure on their chest and shoulders, also some participants wanted more pressure than the machine was able to apply (Krauss, 1987). DTP may not be an effective treatment for everyone and it may be better to apply the pressure when individuals have higher initial anxiety, again suggesting a context-aware system may be beneficial. We also learn that the amount and location of preferred pressure may change per person. However, these findings were for individuals with anxiety, and may not be applicable for those with SPD.

2.5.1.c Weighted Blankets

Weighted blankets are another non-wearable DTP option. In a quasi-experimental design study by Chen et al., the physiological effects of DTP (using a weighted blanket) on anxiety alleviation was evaluated for 12 participants without SPD in a dental setting (2012). The researchers evenly applied 10% of the participants' body weight in order to

apply DTP. Physiological responses were measured using electrodermal activity (EDA) and heart rate variability (HRV) to see if the stimulus would lower the sympathetic nervous system response and increase the parasympathetic nervous system response which can indicate the level of anxiety and arousal. A higher level of skin conductivity level (SCL) indicates higher SNS level which indicates higher anxiety level. The low frequency (LF) band of the heart rate corresponds to mostly to sympathetic activity (SNS), while the high frequency (HF) band corresponds to almost exclusively to parasympathetic activity (PsNS). The LF/HF ratio can be used to indicate the SNS/PsNS ratio. Participants also filled out anxiety questionnaires. Participants lay in the dental chair for 5 minutes before treatments for a baseline. Two phases during the dental cleaning, one without DTP and then one with DTP followed this and were sequentially randomized for participants. Significant differences between the phases were observed in heart rate, LF%, HF%, LF/HF, normalized HR, normalized SCL, and normalized HF%. The results indicate that there is a potential calming (anxiety and arousal reduction) effect from applying DTP (using a weighted blanket) to alleviate anxiety in a dental setting (Chen, Yang, Chi, & Chen, 2013). These results indicate that DTP may be beneficial for anxiety reduction for individuals who are exposed to a stressful stimulus, in this case going to the dentist. Again, this study was conducted with individuals without SPD, so it is unclear if the findings can be applied to this group.

Summary of Non-Wearables

Studies evaluating the effectiveness of non-wearable DTP interventions (i.e.

“Squeeze Machine”) (Grandin, 1992; Edelson et al., 1999); “Hug’m” machine (Krauss, 1987); and weighted blankets (Chen et al., 2012)) found both positive (Chen et al., 2012; Grandin, 1992; Edelson et al., 1999) and non-significant (Krauss, 1987) results. There are several limitations to these studies, in that they use different methodologies, populations, and desired outcomes. More rigorous studies should be conducted with consistent methodologies.

Even with these limitations there are several findings that can provide more understanding about DTP treatment parameters. Grandin’s found that slowly changing pressure and constant pressure are more relaxing than quickly pulsating pressure for her participants (Grandin, 1992). Krauss, although results were non-significant, anecdotally found that some participants wanted different magnitudes and locations for applied pressure (Krauss, 1987). These findings suggest that a treatment should be capable of providing a variety of pressure locations, magnitudes and should be able to provide both constant and slowly changing pressures.

A potential explanation for Krauss’s non-significant results is that the participants did not have high initial anxiety or arousal levels, which makes it difficult to lower these levels further with a treatment (Krauss, 1987). This is a very clear methodological shortcoming. Chen et al. used the stimulus of a dental cleaning to increase participant anxiety levels before applying DTP with a weighted blanket with positive results (Chen et al., 2012). Participants with higher anxiety should be chosen or the treatment should be used when the individual has higher anxiety levels. This is difficult to achieve with non-wearable treatments because they are often so large or heavy that users must travel to

them in order to receive compression therapy, typically by appointment. Wearable alternatives would allow for as needed application of pressure. Additionally, a garment with anxiety sensing capabilities, potentially through heart-rate or ECG etc., could allow for as needed, context aware treatment and lead to more successful therapies.

2.5.2 Weighted Vests

Non-wearable DTP options have been suggested to be effective at reducing anxiety and treating SPD, but have their shortcomings in that they can be large and are immobile. There are several different wearable alternatives, including the commonly used weighted vest. In a survey conducted by Olson and Moulton, 92.2% of OT respondents, who were self-selected, reported recommending the use of weighted vests for treating ASD, and 52.2% reported recommending the treatment for SPD (2004). Various studies have evaluated the effectiveness of these garments ((Fertel-Daly, Bedell, & Hinojosa, 2001); Vandenberg, 2001; Myles et al., 2004; (Kane, Luiselli, Dearborn, & Young, 2004); (Reichow, Barton, Sewell, Good, & Wolery, 2010); and Morrison, 2007) and explored their use by occupational therapists (OTs) (Olson & Moulton, 2004). OTs reported to prescribe the treatment with positive results (Olson & Moulton, 2004), but results from the different studies were mixed. Some were positive (Fertel-Daly et al., 2001; Vandenberg, 2001) and some were non-significant (Kane et al., 2004; Reichow et al., 2009) or mixed (Myles et al., 2004). This may be due to inconsistent treatment procedures, different expected outcomes and target populations (Olson & Moulton, 2004; Morrison, 2007).

2.5.2.a Weighted Vest interventions

Fertel-Daly et al. evaluates the effects of a weighted vest on attention to task and self-stimulatory behaviors using a single subject ABA reversal design in a classroom setting with 5 preschoolers (ranging from 2-4 years old) with pervasive developmental disorders (2001). Four 100g weights are evenly distributed around each vest (approximately 5% of the wearer's body weight) and the garments are worn for a duration of 2 hours and then removed for 2 hours before being worn again. Duration of focused attention to task, number of distractions, and duration and type of self-stimulatory behaviors were recorded during a 5-minute fine motor activity 1.5 hours into wearing the garments (Fertel-Daly et al., 2001).

Positive results were found for all 5 participants. There was an increase in attention and fewer self-stimulatory behaviors when wearing the vest, however the amount of change varied per participant and the changes in behavior did not continue once the vest was removed (Fertel-Daly et al., 2001). This may indicate that DTP treatment results depend on the person, and that the treatment may only be beneficial while the garment is worn.

In a study by VandenBerg, weighted vests were found to have positive effects for on-task behavior for children with ADHD (n=4) (2001). Weight was placed in the weighted vest approximately equivalent to 5% of the wearer's body weight. Vests were worn for 20-30 minutes during the intervention, and behaviors were rated 5 minutes into wearing the garments. All four of the participants had an increase of 18% - 25% for on-task behavior when wearing the vest. Three out of the four participants frequently asked to wear the weighted vest (VandenBerg, 2001).

Other studies evaluating weighted vests did not find a significant link, including Kane et al.'s study evaluating the effectiveness of weighted vests on stereotypy and increased attention to task (2004). N=4 students with ASD were observed in three phases; without wearing the weighted vest, when wearing the weighted vest, and when wearing the vest without weights, in random order (Kane et al., 2004). No improvements were found, and three out of the four participants had negative outcomes. This could be due to increased arousal due to the initial novelty of wearing the garments. The observed period only lasted 10 minutes, which Morrison postulates could be also be a limitation due to a surge in arousal when initially donning the garments that are worn for two hours (Morrison, 2007).

Reichow et al. were also not able to obtain significant results on (n=3, ages 4-5) children with ASD and developmental delays using a weighted vest approach (2009). Participants were observed with no vest as well as with the vest on with and without weights. The dependent variables were engagement, non-engagement, stereotypic behavior, problem behavior, and unable to see child (when coders couldn't see the child's face). The researchers found that weighted vests were not an effective intervention for increased engagement during table-time activities in inclusive classrooms. Limitations of the study include that the long-term effects of the weighted vest were not observed. Reichow et al. highlight the need for future research to examine weighted vest intervention procedures and to establish recommended practices (optimal dosage in weight and duration as well as desired outcomes) for how to use the garments (Reichow et al., 2009).

Myles et al. found mixed results when evaluating three different ABAB single subject design studies using weighted vests (2004). Two of the three evaluated studies were significant, but all used different methods for their intervention, data collection and measured outcomes. Slightly negative effects for on-task behavior, and significantly positive effects for ability to stay seated and deep-pressure seeking behaviors were found (Myles, et al., 2004)

Morrison (2007) completed a review of five studies using weighted vests to treat children on the autism spectrum, (Fertel-Daly et al., 2001; Kane, Wiselli, Dearom, & Young, 2004-2005; Myles et al., 2004; Olsen, L.J. & Moulton, H.J., 2004; Honanker, D., & Rossi, L., 2005). The exclusion criteria were that the participants in the studies needed to be diagnosed with ASD, the deep pressure outcomes needed to be for attention and on-task behavior, and the DTP treatment needed to be a weighted vest rather than a different compression treatment. Morrison concluded that OTs use the vests and find them beneficial, however, evidence to support this is limited. Some reasons for limited evidence include that studies might not have applied the vest for long enough, “It is reported that deep pressure can create an initial surge in arousal before calming begins when used for a period of two hours” (Takagi and Kobayasi, 1955, as cited in Fertel-Daly et al, 2001 as cited in Morrison, 2007). This lack of evidence may also be due to inconsistent procedures. Morrison suggests that, “Research is needed to come up with a standardized protocol to use as a guideline for determining weight and duration of wear for the vest” (2007). This inconsistency can lead to difficulties controlling for outside factors because so many different approaches are used to treat ASD. Additionally,

children with ASD may react to change with stress, anxiety or confusion, so even having the researcher there to observe could be a confounding variable (Morrison, 2007).

2.5.2.b Occupational Therapists' Experiences with Weighted Vests

Olson and Moulton conducted a qualitative phone survey of 51 school-based occupational therapists in order to understand their reported experiences using weighted vests (2004). Data was collected on experiences with diagnoses, the duration of wear, amount of weight, and settings vests were used in. 92.2% of the respondents, self-selected OTs, reported recommending the use of weighted vests for treating ASD, and 52.2% reported recommending the treatment for SPD (Olson & Moulton, 2004).

The procedures used by OTs in practice vary. Most therapists distributed weight evenly and gradually increased the weight until they saw an effect. A range from 2% - 10% of the child's body weight and 2-4 lbs. were used. Garments were worn between 10 and 45 minutes or even a few hours and used with a frequency of two to four times per day depending on the activities the child participated in. Some OTs let the children wear the vest as often as they want, but for a limited amount of time (20 minutes). The reported protocol for amount, frequency and duration of weighted vests, used by OTs is not standardized (Olson & Moulton, 2004). Morrison commented that this inconsistency, "serves to illustrate the need for further research on the weighted vest and development of a standard protocol" (2007).

Positive responses to the DTP therapy that were observed by OTs included calming, increased attention to task, and decrease in self-stimulatory behaviors, decreased rocking, and increased eye contact for children with ASD. Hitting and temper tantrums

were reported to decrease with the use of the weighted vest for children with SPD.

Changes in balance and stability were also reported for those with SPD and ADHD (Olson & Moulton, 2004).

There were several reported concerns with weighted vests. OTs reported that it was challenging to remove the weighted vest in the middle of an activity, “At times, it is too difficult to take the vest off in a transition or in the middle of an activity” (Olson & Moulton, 2004). This is a problem that can lead to pressure habituation, which was also reported to be a concern for OTs. Habituation is defined as “becoming so accustomed to a physical experience that the initial changes noted in the behavior cease to occur as the body makes accommodations to the change” (Olson & Moulton, 2004). However, of the OTs who implemented the vests for longer periods, none of them observed habituation to the pressure, suggesting that more research should be done in this area also. Additionally, OTs expressed their concerns about the weight leading to biomechanical stress. Also, some OTs reported recommending weighted vests for home use, but others voiced their concern that the weighted vests would be misused (Olson & Moulton, 2004).

There are several key takeaways from Olson and Moulton’s study. OTs are not using consistent protocol when using weighted vests as an intervention, but they are finding benefits from the therapy. The OTs also have several concerns, including habituation to pressure. However, the OTs also indicated that it was disruptive to doff weighted vests during activities and transitions, so the garments were sometimes left on the wearer. Weights leading to biomechanical stress on the child and not being able to monitor proper use at home were also concerns (Olson and Moulton, 2004). These

difficulties should be addressed when developing DTP garments.

Summary of Weighted Vests

OTs report using weighted vests and observing positive results, however studies evaluating their effectiveness are mixed. Positive effects were found for attention to task and self-stimulatory behaviors for pervasive developmental disorders (Fertel-Daly et al., 2001) and on-task behavior for individuals with ADHD (VandenBerg, 2001). However, some findings were non-significant, including stereotypy and increased attention to task for students with ASD (Kane et al., 2004), as well as for engagement, non-engagement, stereotypic behavior, problem behavior for children with ASD (Reichow et al., 2009). OTs reported observing benefits from using weighted vests, however their procedures vary widely (Olson & Moulton, 2004). Some limitations of these studies and use of weighted vests as an intervention include inconsistent treatment procedures (Olson & Moulton, 2004; Morrison, 2007), different expected outcomes as well as target populations (Morrison, 2007). More research with consistent protocols and clear objectives should be conducted.

These studies can, however, also give insight into future DTP garment requirements. First, optimal treatment pressure parameters and context of use are unknown (Olson & Moulton, 2004; Morrison, 2007), so a garment with a broad range of repeatable and controllable pressure capabilities and the ability to monitor outcomes could help to systematically answer these questions. This would also help with the OTs' concern for at home misuse (Olson and Moulton, 2004). Additionally, habituation and

difficulty doffing garments were identified as concerns for OTs (Olson & Moulton, 2004). A garment capable of alleviating pressure without requiring doffing could solve these problems. Finally, biomechanical stress caused by weights was also acknowledged as a user safety concern for OTs (Olson and Moulton, 2004). A future therapy garment should provide DTP without using weights.

2.5.3 Other DTP Garments (splints, sleeves and compression vests, pneumatic vests)

Beyond weighted vests, there are other wearable DTP options. These include pneumatic garments (Watkins & Sparling, 2014), arm splints (McClure & Holtz-Yotz, 1991), and stretch garments with negative ease (Zissermann, 1992). Results are mixed.

2.5.3.a Pneumatic Vests

Watkins and Sparling evaluate the effectiveness of the snug vest (an inflatable garment) on stereotypic behaviors for (n=3) children with ASD (2014). The vest's airbag distributes pressure to the shoulders, back and sides without constricting the chest or the stomach. Participants were observed with the garment inflated (20 minutes), with the garment deflated, and with no garment. The vest failed to reduce stereotypy in any of the participants. This may be due to insufficient duration of wear, however, the user manual states that the vest should not be worn longer than 20 minutes (Watkins and Sparling, 2014). The researchers stress the importance of understanding and standardizing the optimal duration of use for DTP interventions. Additionally, the researchers only evaluated the vest's effects on stereotypic behavior rather than other outcomes, such as anxiety (Watkins and Sparling, 2014).

2.5.3.b Arm Splints

In a case study by McClure and Holtz-Yots, foam arm splints were used to apply

pressure to the arms of a child with autism (1991). This resulted in the positive effects of decreased self-injurious behavior, increased social interaction, a calmer behavioral state, and strong desire to wear the pressure garments, which were observed by hospital staff (McClure & Holtz-Yotz, 1991).

2.5.3.c Elastic Garments

Zisserman found mixed results when evaluating the effects of deep pressure on self-stimulating behaviors for a child with ASD and other disorders (1992). The garments that were used were tight fitting gloves and then a compression vest worn under the participant's clothes. The child was observed with both sleeves on and off, one the same day, and then for 9 weeks with and without the garment. Positive results were observed when the child was wearing the sleeves, however self-stimulating behavior and hitting the tabletop increased while the pressure garment, rather than the sleeves, was worn (Zisserman, 1992). The researcher postulates that perhaps the observed behaviors were not self-stimulatory (would be effected by DTP), but rather a means to communicate or explore. This requires further research (Zisserman, 1992). A limitation to this study was that it was with only one participant.

Through a review of non-weighted vest wearable options, including pneumatic garments (Watkins and Sparling, 2014), arm splints (McClure & Holtz-Yotz, 1991), and stretch garments with negative ease (Zisserman, 1992), mixed results on the treatments effectiveness are found. This may be due to insufficient wear-time or limited measures of successful outcomes (Watkins and Sparling, 2014). It also become evident that DTP is applied in different areas on the body, but the chest and stomach should have reduced pressure applied in order to protect vital organs (Watkins and Sparling, 2014).

Limitations to these studies include only using one participant (Zisserman, 1992), and limiting choices to measure success (Watkins and Sparling, 2014).

2.6 Systematic Reviews of DTP Studies

In general, there is a lack of consensus regarding the “optimal” treatment for SPD. This is evident in meta studies of DTP that have been previously conducted (Case-Smith et al., 2015; Watling & Hauer, 2015). In a systematic review of literature published between 2000 and 2012, Case-Smith, Weaver and Fristad examined 5 studies evaluating the effects of sensory integration therapy, and 14 evaluating the effect of sensory-based interventions (SBIs) for children on the autism spectrum with sensory processing problems (2015). The researchers found that sensory interventions, which include DTP therapy, used in current practice “apply different theoretic constructs, focus on different goals, use a variety of sensory modalities and involve markedly disparate procedures” (Case-Smith, Weaver, & Fristad, 2015).

In a review of literature published between January 2006 and April 2013, Watling and Hauer examine the research from 23 studies evaluating the effectiveness of ASI and SBIs for people on the autism spectrum (2015). They found moderate evidence to support ASI and mixed results for SBIs, which include weighted vests, but did not find evidence to support the use of weighted vest for occupational therapy outcomes. Watling and Hauer note that the inconsistent findings within both systematic reviews and studies related to sensory integration might be related to extreme methodological inconsistencies. They note that, “the literature surrounding sensory interventions is complicated by the lack of uniform definitions for critical terms, lack of manualized approaches to the

interventions themselves, inconsistency in inclusion criteria, and variability in targeted outcomes” (Watling & Hauer, 2015). This may suggest that a garment capable of repeatable compression could be used to standardize a protocol and determine if compression therapy is beneficial.

The researchers also suggest that application of sensory integration and SBIs should be guided by the individual and their sensory processing patterns and desired outcomes (Watling & Hauer, 2015). A garment with a broad range of capabilities for the magnitude, duration, and location of applied pressure could be used to create individualized treatments for those suffering from SPD.

From systematic reviews of studies using DTP we learn that some of the inconsistency in findings may be due to methodological inconsistencies (Case-Smith, et al., 2015; Watling & Hauer, 2015). Researchers have suggested that protocol should be standardized (Case-Smith et al., 2015; Watling & Hauer, 2015), however there may not be one optimal protocol as individuals may require different magnitudes, locations and types of pressure (Olson and Moulton, 2004). A garment capable of repeatable DTP treatments could be used to dispel some of the uncertainties and help discover optimal treatment parameters. Additionally, a garment for SPD may need to be customizable for individual DTP needs.

2.7 Gaps in Literature / Understanding

The effectiveness of DTP as an intervention needs further investigation: some researchers suggest a benefit (Ayres, 1972; Edelson et al., 1999; Fertel-Daly et al., 2001; Grandin, 1992; McClure and Holtz-Yotz, 1991; and Vandenberg, 2001; Myles et al. 2004; Olson

and Moulton, 2004; Chen et al., 2012; Poon et al., 2014), whereas others found no significant link (Krauss, 1987; Kane et al., 2004; Myles et al. 2004; Morrison, 2007; Reichow et al, 2009; Watkins N., & Sparling, E., 2014). This inconsistency may partly be caused by the lack of standardized protocol used in research studies (Morrison, 2007; Case-Smith et al., 2015). Morrison argues that a lack of standardization in treatment may explain the deficiency of definitive evidence in the effectiveness of DTP, and that further research is necessary to determine weight and duration of wear standards (2007). Case-Smith et al. supports this claim by commenting that current sensory intervention practices “use a variety of sensory modalities, and involve markedly disparate procedures” (2015).

Other reasons for varying results could include inconsistent qualification criteria for participants (Green & Ben-Sasson, 2010), the application of different theoretical constructs (Case-Smith, Weaver, & Fristad, 2015), insufficiently rigorous study designs (Green & Ben-Sasson, 2010) as well as general confusion (Watling and Hauer, 2015). Green & Ben-Sasson argue the need for more rigorous evidence provided by randomized controlled treatment designs and larger samples (2010). Further, DTP treatment outcomes are often subjective, difficult to quantify and inconsistent. Some researchers argue in favor of reduced stereotypic behavior or increased attention as primary indicators of successful intervention (Reichow et al., 2009). Others argue that relative anxiety level and arousal are the most significant indicators of effective treatment (Grandin, 1992; Edelson et al., 1999; Chen et al., 2012).

Watling and Hauer clearly delineate some of the problems with extreme inconsistency in SPD treatment, stating that “the literature surrounding sensory

interventions is complicated by the lack of uniform definitions for critical terms, lack of manualized approaches to the interventions themselves, inconsistency in inclusion criteria, and variability in targeted outcomes. The limitations significantly contribute to the conflicting findings of the reviews as well as of the individual research studies” (Watling & Hauer, 2015). In order to resolve these uncertainties, advanced technologies designed to provide repeatable, tunable, long-term, and contextually pervasive DTP treatments, could provide the standardized measurements that are needed to more fully understand how to implement DTP therapy.

2.8 Treatment Requirements and Procedures

There are many aspects to DTP treatment that are not clear and may require a broad range of capabilities due to the varying needs of individuals with SPD. These include the magnitude of applied pressure for DTP treatment, type of pressure (constant or changing), duration of pressure, time between treatments, and the location of pressure. The autonomy of the wearer, garment sensing as well as functional and comfort requirements may also be important variables, but are not clearly laid out.

2.8.1 Magnitude of Applied Pressure

The magnitude of pressure that DTP treatments apply is unclear. For weighted vest and blanket applications, 2% - 10% of the wearer’s body weight has been used (Reichow et al. 2009; Morrison 2007; Olson & Moulton, 2004), however it is unclear how this weight is distributed over the body. Temple Grandin’s Squeeze Machine allows for 43kg (95lbs.), using air cylinders set to 60psi, to be applied to the sides of the body for adults (Grandin, 1992). Again, the distribution of this force is unclear. Medical-grade

compression garments for other therapeutic purposes range can from 20-60 mmHg in pressure, the upper bound of which is acknowledged to be uncomfortable and difficult to don for patients (Teng & Chou, 2006; Brennan & Miller, 1998). It might also be the case that the magnitude of pressure needed depends on the individual, mood, the time of day, and other environmental factors, and may change over time (Olson & Moulton, 2004; Grandin, 1992; Koomar & Bundy, 1991). Further work needs to be done in order to understand the optimal magnitude, or range, or pressure required for DTP therapy.

2.8.2 Pressure Type

Beyond the magnitude of pressure needed for treatment, the optimal type of pressure (e.g., constant vs. rapid change), is unknown. Grandin found that constant or slowly varying pressure were the most soothing (1992), however some children may prefer light and rapid stimulation (Koomar & Bundy, 1991).

2.8.3 Duration

Recommended duration of wear requirements also vary. Grandin recommends that pressure be applied for at least 5 minutes (Grandin, 1992). OTs have been reported to apply weighted vests between 10 and 45 minutes or even a few hours and used with a frequency of 2 and 4 times per day depending on the activities the child participated in. Some OTs let the children wear the vest as often as they want, but for a limited amount of time (20 minutes) (Olson & Moulton, 2004). It is evident that individuals become acclimated to applied pressure over time (Iggo & Muir 1969; Olson & Moulton, 2004). This is known as habituation, defined as “becoming so accustomed to a physical experience that the initial changes noted in the behavior cease to occur as the body makes

accommodations to the change” (Olson & Moulton, 2004). This means that constant DTP would become ineffective for the wearer, however certain garments are advertised to be worn all day, and OTs in practice leave these garments on the wearer with no time limit (Olson & Moulton, 2004). Of the OTs who implemented weighted vests for longer periods in a study by Olson and Moulton, none of them observed habituation to the pressure, suggesting that more research should be done in this area (2004).

2.8.4 Location

The optimal location of applied pressure is also unknown. Some aim to apply even pressure over the whole body using a weighted blanket in a supine position (Chen et al., 2012), others use circumferential pressure from the mid chest to the ankle (Krauss, 1987), or lateral pressure (Grandin, 1992). However, it has also been indicated that the arms and legs might be preferred to other body areas (Koomar & Bundy, 1991). Snug vest, a pneumatic garment, distributes its pressure targeting the shoulders, back and sides without constricting the chest or the stomach (Waklins and Sparling, 2014) for safety reasons.

2.8.5 Autonomy

It may be important in many cases for the wearer to have autonomy over the pressure applied (Grandin, 1992; Koomar & Bundy; Olson & Moulton, 2004). If the child is in control, he/she selects the location, type of pressure, magnitude and duration of pressure (Koomar & Bundy as cited by Haar, 1998). OTs have reported to promote putting the children in charge of when they want to use the DTP garment (Olson & Moulton, 2004). DTP treatments should accommodate this need.

2.8.6 Garment Sensing

Some OTs reported recommended weighted vests for home use, but others voiced

their concern that the weighted vests would be misused (Olson & Moulton, 2004). By providing garment sensing monitoring of the effectiveness, and proper use of the treatment could be evaluated remotely.

2.8.7 User Comfort

Beyond pressure treatment requirements, comfort, social and aesthetic requirements are important considerations when developing any functional garment (Haar, 1998; Watkins & Dunne, 2015). The look of the garment can affect the acceptance of DTP garment (Haar, 1998). If the garment is obtrusive, it could draw unwanted attention to the wearer. Physical and emotional discomfort may cause non-compliance and the eventual discarding of a garment, thus making the treatment useless.

2.8.8 Summary

There are many variables for DTP treatment that are not optimized. Researchers have both suggested that protocol should be standardized and that it must be individualistic. This is somewhat contradictory, but may indicate that treatment parameters need to be optimized per individual and their needs. A garment with a broad range of pressure capabilities would be necessary. Sensing and controllable actuation could be used to develop a closed loop, context aware system, that could be used to adjust to the individual and their needs in real time.

In order to provide a closed loop system, a garment that is capable of providing controlled and dynamic compression is necessary. Sensors can then be integrated into the system to create a context aware treatment. A dynamic garment without sensors could be used by individuals who are self-aware. Meaning that they understand when they need DTP and what magnitude, location and type of pressure they need. By providing a

controllable and dynamic DTP treatment these individuals would be able to apply treatment as needed.

2.9 DTP Product Limitations

Current DTP treatment products have several efficacy and usability shortcomings. Non-wearable options can be large and immobile (Krauss, 1987; Grandin, 1992; Edelson et al., 1999; and Chen et al., 2012). Of the wearable options, stretch garments with negative ease are low profile and easy to conceal beneath the wearer's clothing, but are only capable of static compression, and can be difficult to don and doff. Weighted vests are bulky and prevent the wearer from performing physical activities while worn. Additionally, OTs have expressed their concerns about the weight having negative effects through biomechanical stress (Olson & Moulton, 2004). They must also be doffed or have weights removed to adjust the pressure. It can be difficult to don these garments when needed due to the emotional state of the wearer or due to scheduled activities (e.g. school). OTs reported that it was difficult to remove the weighted vest in the middle of an activity, "At times, it is too difficult to take the vest off in a transition or in the middle of an activity" (Olson & Moulton, 2004). However, the DTP garments should not be worn constantly because the wearer will acclimate to the pressure, making the treatment ineffective (Iggo & Muir, 1969). A garment that is capable of dynamic compression might help to solve these problems.

Pneumatic garments are capable of dynamic compression, but require a pump and can have an obtrusive form factor. The wearer must apply the pressure himself or herself by pumping up the garment, or the garment requires a motorized pump. It might be

important to have pressure applied at very specific times for the treatment to be effective. If another individual, such as the parent or guardian, teacher or an occupational therapist, must closely monitor the wearer when the garment is adjusted, donned or doffed, the flow of a class or daily life could be constantly interrupted. Also, the wearer might have to self-adjust the garment, but may want to avoid negative social exposure from inflating a garment if they are already anxious due to trouble processing sensory signals. A dynamic garment with adjustable compression and a slim form factor is needed.

2.10 Shape Memory Alloy Activated Compression Garments (SMA-CGs)

Recent research efforts have explored new compression garment designs using modern technologies, with positive results. These studies have demonstrated that it is possible to make a compression garment that is dynamic, controllable, and form fitting, using integrated active materials (Holschuh and Newman, 2015; Holschuh et al., 2015; Holschuh and Newman, 2016; Duvall, 2016) to overcome the usability issues that exist in current compression products. Specifically, garments with shape memory alloy (SMA) springs have been shown to produce controllable counter-pressures by exploiting the shape-changing properties inherent to SMAs (Holschuh et al., 2015).

There are various garments that have incorporated NiTi SMAs, including a self-adjusting garment for individuals with cerebral palsy (Lin, Zhou, & Koo, 2015) and mechanical counter pressure space suit applications using SMA springs (Holschuh and Newman, 2015; Holschuh et al., 2015; Holschuh and Newman, 2016). Integration of SMA fibers as knitted textiles have been explored to enable specific shape-change actuation behaviors dependent on the architecture of the textile structure (Evans, Brei, &

Luntz, 2006); (Abel, Luntz, & Brei, 2013). SMA actuators have also been used to create aesthetic effects for fashion garments, such as the Skorpions, Kukkia, and Vilkas garments from XS Labs (Berzowska & Coelho, Kukkia and vilkas: Kinetic electronic garments, 2005) (Berzowska, et al., 2008).

2.11 First Research Objective

A major problem facing DTP treatments and research aiming to validate the treatments is the large number of unknowns in DTP therapy procedures (Morrison, 2007). The optimal magnitude, duration and location of applied pressure are all unclear (Morrison, 2007). This means that there is no standard with which to base DTP garment development. Therefore, the first research objective of this thesis is to investigate and quantify the best-known practices for SPD treatment in order to develop prescriptive requirements for optimal future DTP garment design.

2.12 Second Research Objective

The second objective of this thesis is to develop and test a DTP garment that leverages active materials and is designed around the requirements generated from the first research objective. This garment can be used to provide customized treatments and utilized as a tool to standardize treatment protocol.

CHAPTER 3. INVESTIGATION OF SPD TREATMENT REQUIREMENTS THROUGH QUANTITATIVE AND QUALITATIVE MEANS

In order to more fully understand the state and limitations of current DTP treatments and to build a set of requirements for a DTP garment, both a quantitative and

qualitative investigation were conducted. First, occupational therapists (OTs) were interviewed in order to understand their compression therapy practices for treating SPD. Additionally, the pressure distributions generated by existing DTP products were measured using a spatial pressure measurement system. The methods and results are outlined in this chapter, culminating in a set of proposed garment requirements.

3.1 A Qualitative Investigation of Current Practices Used by Occupational Therapists

First a qualitative investigation of current DTP treatment practices was conducted through interviews of occupational therapists (OTs). OTs often prescribe DTP as a treatment for SPD (Watling et al., 1999). Occupational therapy is a form of therapy for those recuperating from physical or mental illness that encourages rehabilitation through the performance of activities required in daily life. Protocol that OTs use for prescribing DTP therapy is a very thorough and individualistic process where the OT works closely with the individual with SPD to determine the best treatments (Olson & Moulton, 2004). However, this protocol is not standardized which may in part cause the inconsistent evidence supporting DTP as an intervention (Morrison, 2007). Effectiveness of treatments are evaluated through a trial and error process where the OT make clinical observations of the behavior of the individual and change treatments depending upon their observations (Olson & Moulton, 2004). DTP treatment requirements and procedures for applied pressure, duration of wear and location of applied pressure are limited and inconsistent, which leave no clear guidelines for developing a DTP treatment garment (Morrison, 2007; Case-Smith et al., 2015).

; Watling & Hauer, 2015).

3.1.1 Qualitative Interview Procedures

Interviews were conducted with OTs in order to more fully understand current procedures and limitations of DTP treatments for SPD. Six OTs and one non-OT autism researcher participated in the interviews. These included;

1. Patricia Orme, OTR/L
2. Peggy Martin, PhD, OTR/L (Program Director)¹
3. Laura Sopeth, MOTR/L¹
4. Leann Shore, OTD, MEd, OTR/L¹
5. Jean Bannick, MOTR/L²
6. Andrea Howard, COTA/L²

LouAnne Boyd PhD, who is not an OT but working on research for autistic individuals, was also interviewed.

The interviews were conducted in person at their place of work for all the experts when possible. One interview was conducted by phone due to geographical restrictions. The interviews were conducted as exploratory conversations. The interviewer took notes during the interview. During the interviews, the experts were asked about the experiences they had with DTP and compression therapy. They were asked about the types of garments that were used and their procedures for use. The variables that emerged as important when structuring a treatment protocol included the magnitude of pressure,

¹ Members of the University of Minnesota Faculty in the Department of Rehabilitation

² OTs from the Center for Speech Language and Learning

type of pressure (constant or modulating pressure), location of pressure, circumstances that affect the treatment (time of day etc.), duration of the treatment, comfort needs, and social needs. The OTs were also asked what they would want in an ideal compression garment system. After the interviews, the notes were typed up. Initial categories emerged from the data, which were checked between the different interview. After the initial analysis, the experts were emailed with notes from the meetings or met with in person to confirm the findings and clarify questions. The categories were adjusted to include these clarifications and added notes.

3.2.2. Participants' Experiences with DTP Therapies

The OTs that were interviewed work with several different DTP products including weighted vests, other weighted products and tight-fitting stretch garments with negative ease (the difference between the measurements of the body and the measurements of the garment). None work with pneumatic garments.

The OTs from the University of Minnesota Department of Rehabilitation Medicine have experience with compression products including the use of hip huggers for children with low tone and pelvic instability as well as the occasional use of weighted vests and blankets. The hip huggers were used for helping to stabilize the pelvis and hips so children could maintain a four point or standing posture without abduction of the hips. The weighted vests were used for children with hypo-responsivity to provide proprioceptive sensory input and for children with modulation difficulties. They also had experience with helmets possibly creating a calming effect, but this is anecdotal. Additionally, the OTs had experience using weighted blankets to reduce anxiety and promote sleep in elderly populations.

Patricia Orme has mostly seen and worked with neoprene vests and Lycra garments worn under the child's clothing that apply pressure to the torso or torso and arms.

The OTs at the Center for Speech Language and Learning (CSLL), Jean Bannick and Andrea Howard, use several DTP products and methods to treat SPD. These include weighted hats, leg pads, weighted blankets, weighted vests, weights hung around the shoulder and arms as well as massage.

Lou-Anne Boyd previously worked with children displaying sensory processing problems in the Anne Arundel County schools in Maryland. Boyd was trained in the dry brush technique (a somewhat controversial technique) (Wilbarger, 1995) and was responsible for supporting the training of other specialists. Boyd has worked with wetsuit/stretch type negative ease garments as well as weighted vests made from fishing vests and beanbags.

Table 1: Experts and their experiences

Expert	Weighted Products	Stretch / Negative Ease Products	Pneumatic	Other
Patricia Orme	Yes	Yes	No	NA
UMN OTs	Yes - Weighted vests provide proprioceptive sensory input and for children with modulation difficulties as well as weighted blankets for elderly populations	Yes - Compression products for children with low tone and pelvic instability	No	Yes - Helmet
CSLL OTs	Yes - Weighted hats, leg pads, weighted blankets, weighted vests, and weights hung around the	No	No	Yes - Massage

	shoulders			
LouAnne Boyd	Yes	Yes	No	Yes - Brushing

3.1.3 Results

Variables that emerged as important to consider for DTP treatment include DTP therapy procedures, judging treatment effectiveness, pressure location, magnitude, modulation, and duration, metric unknowns, social aspects, comfort, autonomy, feedback loop, as well as cost and sizing. Some variables emerged as more important than others when they were discussed by more than one OT.

Compression Therapy Procedures

Treatment for SPD is a very anecdotal process, meaning that the OT tries out a therapy and “sees how it goes” (UMN OTs). Compression therapy success is currently tested using outcomes (UMN OTs). The procedure of prescribing compression for SPD is variable and individualistic. It is an in-depth process with each child (UMN OTs). The OTs at the CSLL administer compression when the child looks “tense.” They also noted that the protocol is very individualistic and depends on the child, and said that, “there is no exact science” and that, “It’s different every day” (Jean Bannick - CSLL). A treatment capable of providing customizable options could help with this very individualistic process, and perhaps be used as a tool to determine optimal procedures in a more systematic way.

Judging Treatment Effectiveness

Treatment effectiveness was measured through observation. For instance, the OTs would remove pressure once the patient “calmed” (UMN OTs). This knowledge for judging the treatment’s success and to help determine when to adjust or end the treatment (e.g. DTP) depends on the expertise of the OT. Some of the OTs were concerned that when compression products were brought home they would be improperly used (CSLL). Additionally, the OTs mentioned that compression garments are often misused in classrooms (UMN OTs). This could possibly be prevented if there were other ways to measure success and need, for instance with a physiological sensor and context aware system.

Location

Some of the OTs have used neoprene stretch garments (Laura Sopeth; Patricia Orme), which apply pressure to the torso, as well as weighted vests and other weighted products (Jean Bannick), which apply pressure to the shoulders. Patricia Orme also noted that the shoulders might be an important area for DTP. Beyond the torso, other areas of the body that might be important for compression include the head, which might have the possibility of reducing self-injurious head banging behavior (Laura Sopeth), as well as the legs and arms (Patricia Orme; Jean Bannick). It is not clear which is the most optimal location and under which circumstances these locations should be chosen.

Magnitude

The optimal magnitude of pressure needed for DTP treatments is unclear (UMN OTS). 10% of the wearer's body weight is typically used for weighted products for people with SPD, but the exact magnitude of pressure that is applied is unclear, because the distribution of weight is unknown (UMN OTs; Jean Bannick). Additionally, some people with SPD want very loose clothing rather than compressive clothing (UMN OTs). The desired magnitude of pressure may also change based on many different factors including the day (Jean Bannick) and individual (Jean Bannick; UMN OTs). Determining the outer limit for applied pressure would be critical in order to prevent discomfort or harm of the wearer (UMN OTs; Patricia Orme). Therefore, a garment capable of providing a range of pressures, under the threshold of discomfort, would be beneficial.

Type

Beyond providing a range of static pressures, possibilities of slowly changing pressure would be highly beneficial in DTP treatments. Many current garments (e.g. neoprene stretch vests) typically applying one pressure, but a garment that could apply small increments of increasing pressure might be useful (Patricia Orme). Some treatments (e.g. massage with the hands) slowly apply pressure to the body (Jean Bannick). Gradually changing pressure was observed to be less threatening than quickly applied pressure (Jean Bannick). It has also been found that slowly changing and constant pressure are more relaxing than quickly changing

pressure (Grandin, 1992). The ability to reduce or remove the pressure between treatments as well as increase the pressure slowly over time would also help to prevent pressure acclimation, which can cause the treatment to be useless (UMN OTs), without having to doff the garment, which can be difficult and disruptive (Patricia Orme).

Duration

As with many of the important design requirements for DTP treatment, optimal duration is also unknown. Some reported metrics used by OTs include 20 to 30 minutes for neoprene vests (Patricia Orme), and two-hour intervals for weighted vest with no time limit for weighted blankets (OTs at the CSLL). The optimal duration for some is judged sufficient if the individual has worn the garment “until they've calmed” (UMN OTs), this is reported to be ~10 minutes but only based on anecdotal evidence. These inconsistencies and uncertainties in the optimal duration of the pressure treatment dosage and additionally in the time between treatments are important to clarify in order to provide the best therapeutic treatments for DTP (UMN OTs). Additionally, the body habituates to applied pressure, so the effectiveness of the treatment wears off (Patricia Orme; UMN OTs). To further confuse the matter, some children like to always have the DTP garments on (Patricia Orme). Some teachers have the children wear weighted products all the time. They “hand them out like candy,” which is not useful (UMN OTs). More clearly understanding optimal duration of the treatment, without reaching

habituation, and clarifying the appropriate amount of time between treatments is critical to provide an effective therapeutic treatment for SPD. A garment that is capable of providing repeatable and programmable treatment without having to doff the garment would be beneficial.

Factors that require further study

The experts had several different suggestions for future research and DTP garment development. It is important to more clearly understand the treatment unknowns, in order to determine the optimal treatment duration, timing between treatments, and magnitude of pressure (UMN OTs). Location of pressure and modulation of pressure are also important variables that are not fully understood. A garment with broad capabilities for magnitude, duration, and location of pressure would be useful to answer some of the unknowns about compression therapy (UMN OTs; Jean Bannick).

Social Aspects

Beyond the pressure requirements for a DTP treatment we must also consider social aspects of dress. Once children reach elementary school age they begin to care about how their clothing looks (Patricia Orme). Garments that draw unwanted attention could make a difficult situation worse. By either having the garment hidden underneath the clothing or look like something cool (e.g. a jean vest or dress up) this problem could be solved (Patricia Orme).

User Comfort

Wearer comfort is also important for this population. Scratchy materials may bother the wearer (Haar, 1998) as well as high necklines (Patricia Orme). Thermal comfort is also an important variable (CSLL; Patricia Orme). Children may become hot in the summer (Patricia Orme). Material and patterning choices should be centered on the user and their comfort and functional needs.

Autonomy

Another important variable is that personal control, or autonomy, over the garment and themselves (Patricia Orme; UMN OTs; Grandin, 1992). The garment should allow the wearer to control the pressure that is being applied to their body. A DTP garment capable of dynamic compression might be better for teenagers, who have self-awareness (UMN OTs).

Feedback

Incorporating pressure and physiological sensors into the garment might also be important for understanding treatments and their effectiveness (UMN OTs). OTs mentioned that they would want to know how the treatment was working at home by having a sensor incorporated into the system to monitor the individual with SPD (CSLL OTs). Additionally, beyond measuring effectiveness, sensors incorporated into the system could allow for context aware treatments. They would be able to sense the need, provide the treatment, then measure treatment effectiveness. Over

time this could be used to develop optimal DTP therapies.

Cost and sizing

Cost and sizing are other big problems with DTP products. It is difficult to fit a garment to a child that is growing quickly (Jean Bannick). Adjustability may be a way to reduce the number of sizes.

Ideal future garment

A treatment garment for SPS should accommodate these variables outlined through the literature and through talking with OTs. The garment should have the ability to apply various pressure magnitudes, durations, and types (e.g. slowly changing and constant) without doffing the garment. It should support user autonomy and be socially acceptable to wear (through being hidden or looking cool). The garment should also be comfortable and easy to don and doff. The garment would ideally be context aware.

Table 2: Interview Data

Variable	Requirement / Suggestion and Source
When DTP is used	<ul style="list-style-type: none"> • Process is anecdotal and tested on outcomes currently (UMN OTs) • Procedures for prescribing DTP therapies for SPD are variable, in depth and individualistic (UMN OTs; CSLL). It was noted, "there is no exact science" and that, "it's different every day" (CSLL). • Pressure is applied when the child looks tense (CSLL)
Difficulties with existing products	<ul style="list-style-type: none"> • Stretch garment provide only one pressure (LouAnne) • Garments are difficult to don / doff when change in pressure is required (Patricia Orme; Boyd)
Location	The most optimal location and circumstances these locations should be chosen are

	<p>unclear (Morrison, 2007). Possible locations include:</p> <ul style="list-style-type: none"> • Torso (Laura Sopeth; Patricia Orme), • Shoulders (Patricia Orme; Jean Bannick) • Head (Laura Sopeth; Orme) • Back (Orme) • Legs (Patric Orme; Jean Bannick; Orme) • Arms (Patric Orme; Jean Bannick; Orme) • As much of the skin possible (Boyd) • Palms / hands / feet (Boyd)
Magnitude	<p>The optimal magnitude of pressure needed for DTP treatments is unclear (UMN OTs).</p> <ul style="list-style-type: none"> • 10% of the wearer's body weight (UMN OTs; Jean Bannick) • Some people with SPD want very loose clothing rather than compressive clothing (UMN OTs) • Magnitude may change based on many different factors including the day (Jean Bannick) and individual (Jean Bannick; UMN OTs) • Determining the outer limit for applied pressure is critical (UMN OTs; Patricia Orme)
Type	<ul style="list-style-type: none"> • Slowly changing pressure is less threatening (Jean Bannick) • Changing pressure (slowly increasing over time and ability to remove the pressure) could help prevent acclimation (UMN OTs; Patricia Orme)
Duration	<ul style="list-style-type: none"> • 20-30 minutes - neoprene vests (Patricia Orme), • 2-hour limit - weighted vests (OTs at the CSLL). • No time limit - weighted blankets (OTs at the CSLL). • "Until they've calmed," which is reported to be ~10 minutes but only based on anecdotal evidence (UMN OTs) • Apply repeatedly - Maybe 3-5 minutes per time (LouAnne Boyd)
Habituation	<ul style="list-style-type: none"> • Habituation to applied pressure, so the effectiveness wears off (Patricia Orme; UMN OTs) • Concern that some teachers have the children wear weighted products all the time - they "hand them out like candy" (UMN OTs)
Factors that Require Further Study	<ul style="list-style-type: none"> • It is important to more clearly understand the treatment unknowns, in order to determine the optimal treatment duration, timing between treatments, and magnitude of pressure (UMN OTs) • Location of pressure and modulation of pressure are also important variables that are not fully understood. A garment with broad capabilities for magnitude, duration, and location of pressure would be useful to answer some of the unknowns about compression therapy (UMN OTs; Jean Bannick)
Social Aspects	<ul style="list-style-type: none"> • Once children reach elementary school age they begin to care about how their clothing looks (Patricia Orme) • Garments that draw unwanted attention could make a difficult situation worse (Patricia Orme) • By having the garment hidden underneath the clothing or look like something cool (e.g. a jean vest or dress up) this problem could be solved

	(Patricia Orme)
Comfort	<ul style="list-style-type: none"> • Scratchy materials may bother the wearer (Haar, 1998) • High necklines may bother the wearer (Patricia Orme) • Thermal comfort (CSLL) • Kids get hot in neoprene (winter vs. summer) (Patricia Orme)
Donning and doffing	<ul style="list-style-type: none"> • Doffing the garment can be difficult and disruptive (Patricia Orme)
Autonomy	<ul style="list-style-type: none"> • Personal control, or autonomy, over the garment and themselves is important (Patricia Orme; UMN OTs; LouAnne Boyd; Grandin, 1992) • A DTP garment capable of dynamic compression might be better for teenagers, who have self-awareness (UMN OTs)
Feedback	<p>Incorporating physiological sensors would be useful to:</p> <ul style="list-style-type: none"> • Monitor at-home use (CSLL) • Evaluate the treatment's effectiveness (UMN OTs) • Provide context aware sensory diets (Boyd)
Cost / Sizing	It is difficult to fit a garment to a growing population with DTP products in a cost-effective way (Jean Bannick).
Ideal Future Garment	<ul style="list-style-type: none"> • Incorporating physiological sensors (e.g. heart rate) (CSLL; UMN OTs; Boyd) • The garment should have the ability to apply various pressure magnitudes, durations, and types (e.g. slowly changing and constant) (CSLL; Orme; UMN OTs; Boyd) • It should support user autonomy (UMN OTs; Boyd) • Be socially acceptable to wear (through being hidden or looking cool) (Orme) • Comfortable (Orme; CSLL) • Easy removal of pressure (UMN OTs; CSLL; Orme; Boyd)

3.1.4 Summary

Through the interviews with experts, important variables emerged, including therapy procedures, judging treatment effectiveness, pressure location, magnitude, modulation, and duration, metric unknowns, social aspects, comfort, autonomy, feedback loop, as well as cost and sizing. However, optimal treatment metrics for DTP therapy were still unclear. Many variables (e.g. duration, location, and magnitude of pressure etc.) were indicated to require a broad range of capabilities, either in order to meet user's various needs or because the optimal parameters were not known by the experts. In order to understand the ways that these pressure variables are being met in current practice a

quantitative evaluation of the pressure outputs of existing products should also be conducted. This quantitative study is outlined in section 3.2.

3.2 Quantifying Existing DTP Treatments

There are several DTP products for treating SPD. These include non-wearable options, including the Squeeze Machine (Grandin, 1992; Edelson et al., 1999), the “Hug’m” apparatus (Krauss, 1987), and weighted blankets (Chen et al., 2012), as well as wearable options, such as weighted vests (Olson & Moulton, 2004), pneumatic garments (Watkins and Sparling, 2014), arm splints (McClure & Holtz-Yotz, 1991), and stretch garments with negative ease (Zisserman, 1992). However, the treatments these products are providing, specifically the pressure magnitudes and locations, are not clear. In this section, we seek to quantify the performance of three different wearable DTP options, a weighted vest, a stretch vest with negative ease, and a pneumatic vest, in order to more clearly understand what treatments are currently offered through the use of these products. The data collection methods using a spatial pressure measurement system, results and a discussion of the limitations of these treatments are outlined in this section.

3.2.1 DTP garments chosen for testing

Relative pressure distribution was collected for three different available DTP treatments garments, a weighted garment, negative ease stretch garment, and a pneumatic garment. The weighted and negative ease stretch garments were chosen with the input of OTs. None of the OTs had used a pneumatic garment, so the vest was chosen from three available options claiming to treat SPD. The garment was chosen based on its

performance, availability in the testing mannequin's size, and its cost.

The garments were purchased from different brands, with different sizing systems. Garments were chosen based on the mannequin's measurements. The weighted vest was chosen in size XS, the stretch vest in size 54, and the pneumatic garment in size XXS. These garments have different labeled sizes, but their dimensions correspond to those of the test mannequin, size 3T.

3.2.1.a Weighted vest (Southpaw)



Figure 7: Southpaw weighted vest

(Weighted Vests, n.d.)

The weighted vest was bought in size XS. The weights should be placed in pockets before donning the garment. The vest should not be used during strenuous physical activity, such as “running, jumping, turning upside down or any activity involving sudden movements, except in carefully monitored instances” (Weighted Vests, n.d.).

Fit. The garment incorporates hook and loop tape for adjustability and a zipper as a closure. There is no information on how to properly adjust the size of the garment for the wearer.

Magnitude. The garment has several different weight options (.5lb, .75lb, and 1lb).

Location. The weights are labeled and should be placed in the 4 different pockets with weight distributed equally. Pocket locations are sewn to prevent the weights from pressing on the spine.

Duration. There is no information provided on the duration of wear for the garment.

3.2.1.b Stretch vest (SPIO)



Figure 8: SPIO stretch negative ease vest

(Classic TLSO, n.d.)

The negative ease stretch vest from SPIO was bought in a size 54 for \$220 USD.

Instructions are provided with the garment.

Fit. In order to achieve adequate-fit the individual donning the garment should be able “place a hand between the child’s body (in the trunk area) and SPIO and feel significant resistance when you pull your hand away from the child’s body.

Approximately an inch resistance is adequate” (Classic TLSO, n.d.)

Magnitude. The garment only applies one magnitude of pressure if properly fit to the wearer. The magnitude of this pressure is unknown.

Location. The garment aims to evenly distribute pressure on the trunk of the wearer.

Duration. According to the manual, the garment can be worn all day except when the wearer is sleeping or when they are submerged in chlorine.

3.2.1.c Pneumatic vest (SqueaseWear from Fun and Function)



Figure 9: SqueaseWear Pneumatic vest from Fun and Function

(SQUEASE Inflatable Compression Vest, n.d.)

The pneumatic vest from Fun and Function was bought in a size XXS for \$356 USD. The vest comes with a user manual and an instruction booklet. The instruction booklet has either the user or an adult evaluate the effectiveness of the garment through observation of different variables. The manual encourages the wearer to apply the pressure, so that they have a sense of control.


Fit. In order to find the best fit for the garment, hook and loop tape can be adjusted on either side of the garment. Appropriate fit is defined as when the garment fits loosely around the torso when deflated and leaves a two to three finger width gap between the body and the deflated vest. According to the manual, the vest should provide a “comfortable, firm deep pressure when inflated” (SQUEASE Inflatable Compression Vest, n.d.).



Magnitude. According to the manual, there are several different ways to use the garment depending on the individual. Users who respond strongly to deep pressure are advised to start with a lower level of pressure / inflation and then gradually increase the stimulation amount until the optimal amount of pressure / inflation is found. Another option, for individuals who prefer high levels of pressure stimulation, is to inflate and deflate their vest several times before leaving it deflated. This, according to the manual, has been observed to help with self-regulation. There is a pressure valve that limits the maximum pressure that can be applied, but it is unclear what this pressure is.

Location. The garment aims to evenly distribute pressure.

Duration. There are several suggested ways to choose when to use the vest. These are time related, activity related, and arousal level related. For the best results the manual recommends inflating the garment for 20 minutes, then deflate for a minimum of 20 minutes before inflating the vest again. This is in order to prevent the body from desensitizing to the pressure. The 20-minute inflation period is recommended based on OT observation, but each user may be different and they are encouraged to try inflating it for either less or more time. They also recommend that “you inflate the vest at 2 hour intervals, for approximately 20 minutes each time, irrespective of your stress level at those times” and that “you can also inflate the pressure vest in response to additional stress triggers in the 2 hours between inflation.” Additionally, individuals can wear their vest all day and inflate it when required, but the manual recommends taking it off if it is hot out and putting it on only when needed.

Table 3: Garment specifications

Garment	Size	Cost	Fit	Magnitude	Location	Duration
 Weighted	XS	\$160 USD	No specific directions. There is hook and loop tape for adjustability.	There are different weights for the four pockets in the garment: .5lb, .75lb, and 1lb. The weights should be evenly distributed.	Weights should be evenly distributed. The garment does not apply pressure directly on to the spine.	NA
	54	\$220 USD	1” of resistance when placing a hand between	There is one pressure magnitude if the garment is	Aims to evenly distribute pressure.	Can be worn all day, except when the wearer intends

 Stretch			the child's body (in the trunk area) and SPIO.	appropriately fit to the wearer.		to sleep and when the wearer is immersed in chlorinated water.
 Pneumatic	XXS	\$365 USD	Garment fits loosely around the torso when deflated and leaves a 2 – 3 finger width gap between the body and the deflated vest.	Garment can provide different pressures through bladder inflation. A valve prevents over-inflation. Pressure magnitude is unknown.	Aims to evenly distribute pressure.	2-hour intervals, for approximately 20 minutes each time.

Summary table of the garments

3.2.2 Pressure Sensing

Piezoelectric sensors are a common way to measure pressure amount and distribution on the body. They have been used to measure the interface pressure between pressure garments and burn victim's skin (Mann, E. K., L., & Engrav, 1997; Macintyre, 2011), quantify and evaluate the magnitude and distribution of skin pressure for graduated elastic compression stockings (GCSs) (Liu, et al., 2005) and measure the impact of posture on pressure output (Liu R. , Kwok, Li, T., & Zhang, 2007).

Two different piezoelectric measurement tools were used to collect the data, a spatiotemporal pressure measurement system, Tekscan CONFORMat 5330 pressure sensor mat (Tekscan, Inc., Boston, MA, USA), and temporal spot force sensor, Adafruit's round FSR sensor, product ID166. Limitations of these pressure measurement tools include difficulty accurately calibrating for pressure measurement on the body without

requiring complex and cumbersome equipment (Macintyre, 2011) as well as difficulties wrapping a 2D object around a 3D form without bending and buckling the sensor, creating false pressure readings. Even though they have many limitations, piezoelectric sensors are the state of the art for on body pressure measurement, so were implemented in this study.

3.2.3 Methods: Quantifying Current DTP Treatments

Pressure data was collected for three different garments, a weighted vest, a negative ease stretch vest, and a pneumatic vest, in order to determine their pressure distribution and relative pressure output compared to one another. All three vests were purchased in a size to fit the 3T mannequin used to collect the pressure data. Due to limitations in the sensors' form factor, pressure data was collected for the abdomen and the shoulders for each garment using separate pressure measuring tools. Garments were placed on the mannequin according to the fitting directions for each garment.

3.2.3.a Tekscan Sensor

Spatial pressure distribution data on the abdomen was collected using a Tekscan CONFORMat 5330 pressure sensor mat, with an active sensing region of 471 mm x 471 mm, 1024 sensing elements (sensels), 0.5 sensels / cm², 34 kPa maximum pressure.

While sensors are applied to an inextensible film, circular laser cuts in the sensor mat allow it to conform more easily to the shape of the body (Tekscan, Inc., Boston, MA, USA). Sensor sensitivity was set to high, S-40, in order to achieve a full range of pressure for our application and without over saturating the sensor. The sensor was then equilibrated in a vacuum bag at 30, 90 and 150 mmHg, in order to correct for individual

sensor (sensor cell) degradation over time. Due to lack of advanced equipment (Macintyre, 2011) and difficulties with accurate pressure calibration at low pressure levels (data collected for existing DTP treatments using Tekscan Inc.'s standard protocol), the data was collected as raw data, without a calibration applied. This is not ideal, but still provides relative pressure output and distribution between garments. The sensor mat was centered on a 3T mannequin, so that the center of the sensor was aligned with the center front of the mannequin, and pinned in place. Data for all three garments (weighted, negative ease stretch, and pneumatic) was collected with the same sensor placement in order to compare relative pressure outputs and distributions.



Figure 10: Tekscan Inc. CONFORMat sensor placement on 3T mannequin form for data collection. Mannequin front (left), back (middle), and side (right).

Data was collected over time in the form of 2-dimensional pressure map recordings. Five 60-second captures were taken, with 4 samples of the 2-dimensional map taken per second, were collected with the sensor beneath the negative ease stretch and pneumatic garments. Five captures were collected for each level of weight applied (no weights, .5lb

weights, .75lb weights, and 1lb weights) for the weighted vest and one capture was collected with the sensor mat on the mannequin with no garment applied. The sensing threshold was set to three, the lowest possible. Garments were removed and replaced on the mannequin, or deflated, before each new recording. Garments were fit to the mannequin according to each garment's guidelines, described above.

Weighted

- 5 x 60 seconds with no weight
- 5 x 60 seconds with .5lb weights
- 5 x 60 seconds with .75lb weights
- 5 x 60 seconds with 1lb weights
- Garment was removed and replaced between each recording
- Negative Ease Stretch
 - 5 x 60 seconds
 - Garment was removed and replaced between each recording
 - Hook and loop tape patches are used as markers to create the same fit each time
- Pneumatic
 - 5 x 60 seconds
 - Garment deflated between each recording, then fully inflated 10 seconds into each new recording as quickly as the researcher could pump the garments until fully inflated

3.2.3.b Tekscan Pressure Selection Region

In order to analyze the data, a region on the 2D pressure map was selected that is representative of the front of the compression garments. This removes sensing regions outside of the garment and most of the error created by overlaps in the back of the mannequin when wrapping the sensor mat around the mannequin, which can create false pressure readings from folds and bending of the sensor. A matrix for data of interest was created using the landmarks of the mannequin's side seams and the bottom furthest row that the garments applied compression. The region included columns 6 – 27 (22 sensels) and rows A – P (16 sensels). 352 total sensels were selected. The matrix selection was applied to all pressure data in order to compare relative pressure and distribution.

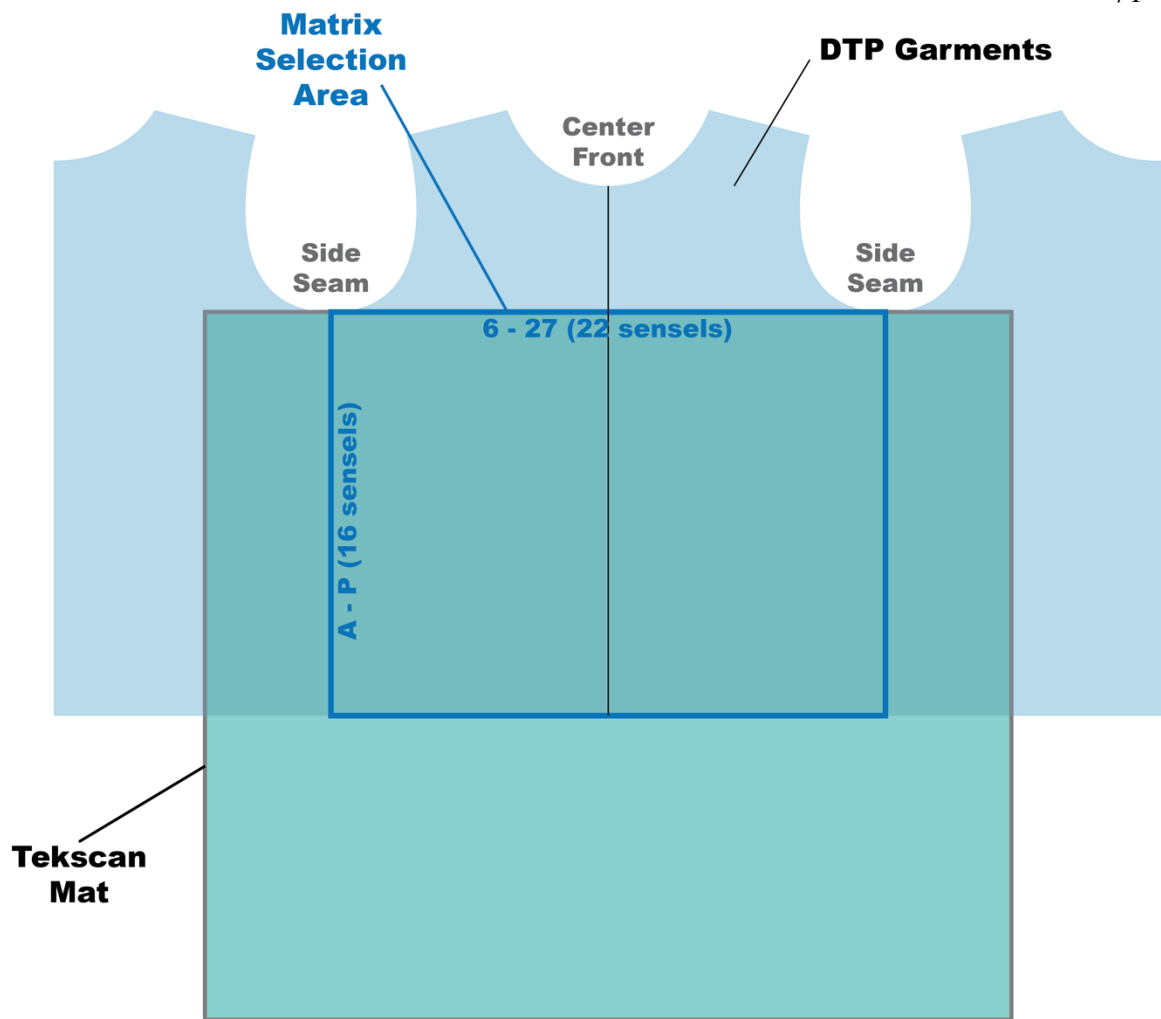


Figure 11: Data collection region in relation to sensor and garment placement (from side seam to side seam and to the lower edge of the garment).

3.2.3.c Tekscan Zeroing Method

The data collected from the pressure mat with no garments applied was subtracted from the pressure data collected for each of the garments, by averaging the no-garment frames over time and then subtracting this from all consecutive tests. This was done in order to remove bias introduced from wrapping the sensor around the mannequin form.

Variance Calculation

Data variance between tests for each garment test case was calculated. The average distribution for the last frame for all five tests (the most stable state of the test) was calculated and then the last frame for each test was subtracted from the average matrix. In order to represent the variance of the data the average of the frobenius norm of the error for each garment test case was computed.

3.2.3.d Tekscan Analysis Methods

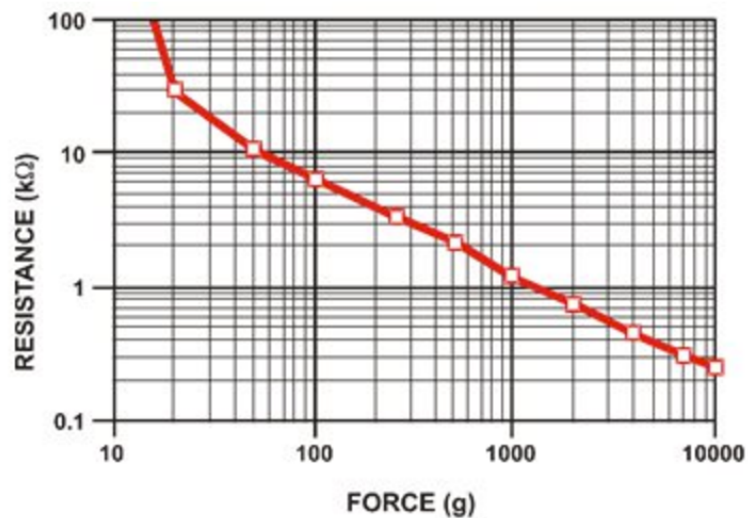
For each garment, the average spatial pressure distribution and average pressure over time are compared. All weight levels are computed and displayed for the weighted vest. Spatial distribution for each garment is displayed using the average final frame matrixes (most stable state of the test) for the 5 tests. Each test's spatial matrix is averaged and displayed over time to calculate the pressure over time for each garment. Average pressure per garment is calculated by averaging the last 20 seconds of all tests.

3.2.3.e Shoulder FSR Data Collection Methods

The weighted vest applies pressure mainly to the shoulders, which is a body area that the Tekscan sensor is unable to accommodate. In order to quantify this pressure, force data was collected from Adafruit's Round Force Sensitive Resistor (FSR), #166, using a DAQ system. Due to variation between sensors during the manufacturing process the same FRS sensor was used for all data collection. The sensor was centered on the 3T mannequin's right shoulder and taped in place. Sensor placement remained the same for all tests. Data was collected over a 60 second interval. This was repeated 5 times per garment, and 5 times per weight in the case of the weighted vest. Each garment was

removed and replaced, or deflated between tests. The pneumatic garment was inflated after 10 seconds of data collection in order to capture a range data if applicable.

The FSR's mean and standard deviation voltage output were calculated for the last 20 seconds of each test. Voltage corresponds to force as represented by the sensor specifications. The data will be reported both as the raw voltage and the corresponding force in pounds.



Force (lb)	Force (N)	FSR Resistance	(FSR + R) Ω	Current thru FSR+R	Voltage across R
None	None	Infinite	Infinite!	0 mA	0V
0.04 lb	0.2 N	30K Ω	40 K Ω	0.13 mA	1.3 V
0.22 lb	1 N	6 K Ω	16 K Ω	0.31 mA	3.1 V
2.2 lb	10 N	1 K Ω	11 K Ω	0.45 mA	4.5 V
22 lb	100 N	250 Ω	10.25 K Ω	0.49 mA	4.9 V

Figure 12: FSR sensor voltage to force output key

(Round Force-Sensitive Resistor (FSR), n.d.)

3.2.4 Results

3.2.4.a Abdomen Distribution

The distribution of pressure over the abdomen also varied per garment. The weighted garment applied focused pressure points on the abdomen that increased as the weights increased, as seen in Figures 13-16. The vest with no weights only had one pressure point on the upper left of the torso. The vest with 0.5lb weights had six concentrated points of pressure scattered on the torso, with those on the left side reporting higher raw pressure values. The 0.75lb vest had six symmetrical pressure point, four of which were lined up on the chest, and two (with higher pressures) lower on the torso and further out to the sides of the mannequin. The vest with 1.0lb weights had two larger concentration points of pressure on the lower torso. This garment also had two non-symmetric points on the chest with lower pressure than the lower torso points. The stretch garment's pressure was evenly distributed in an up-side-down "U" shape over the torso as seen in Figure 17. The pneumatic pressure distribution consisted of larger blobs of pressure across the chest of the mannequin, as seen in Figure 18.

3.2.4.b Magnitude

The magnitude of average applied pressure varied from 0.38 raw pressure units to 10.40 raw pressure units for the different commercial garments. The stretch garment and pneumatic garment had the highest average pressures, with 10.40 and 8.95 raw pressure units respectively. The pneumatic garment was the only able to provide a range of pressures dynamically (in a continuous manner), all other garments had static pressure values. The weighted vest had lower average raw pressures that decreased as the weights decreased, with 3.83 (0lb), 1.46 (0.75lb), 1.30 (0.5lb), and 0.38 (0lb) raw pressure units.

The variance ranged from 3.73% to 19.09% between garments. The weighted vest with 0.75lbs weights had the highest variance (19.09%) and the stretch garment had the lowest variance (3.73%). “Raw pressure units” refer to the uncalibrated pressure output generated using Tekscan’s CONFORMat sensor. These data were not calibrated due to limited time and inadequate calibration procedures for on-body pressure measurement. The raw data can be used to compare relative pressure magnitudes and distributions between garments.

Table 4: Mean Tekscan CONFORMat sensor raw pressure data (Averaged over the last 20 seconds) and variance of data (%) for each DTP garment

Garment	Mean Pressure (Raw units)	Variance (%)
Weighted – 0lbs	0.38	9.11
Weighted – 0.5lbs	1.30	16.20
Weighted – 0.75lbs	1.46	19.09
Weighted – 1.0lbs	3.83	13.55
Stretch	10.40	3.73
Pneumatic	8.95	5.43

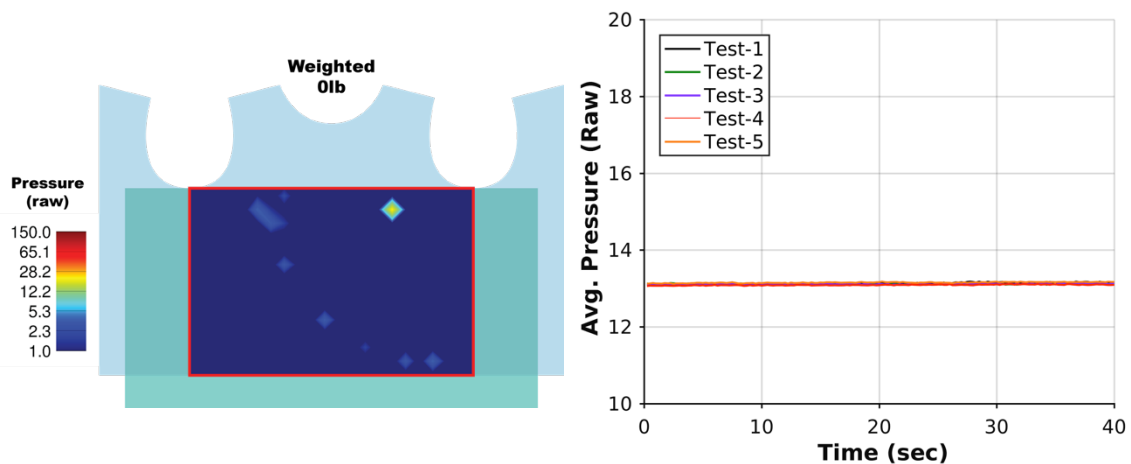


Figure 13: Average (between 5 tests) spatial raw pressure distribution (left) and average pressure over time (right) for the weighted vest (0lbs). *Useful for relative comparisons and to understand special distributions, but not useful for determining absolute pressure levels*

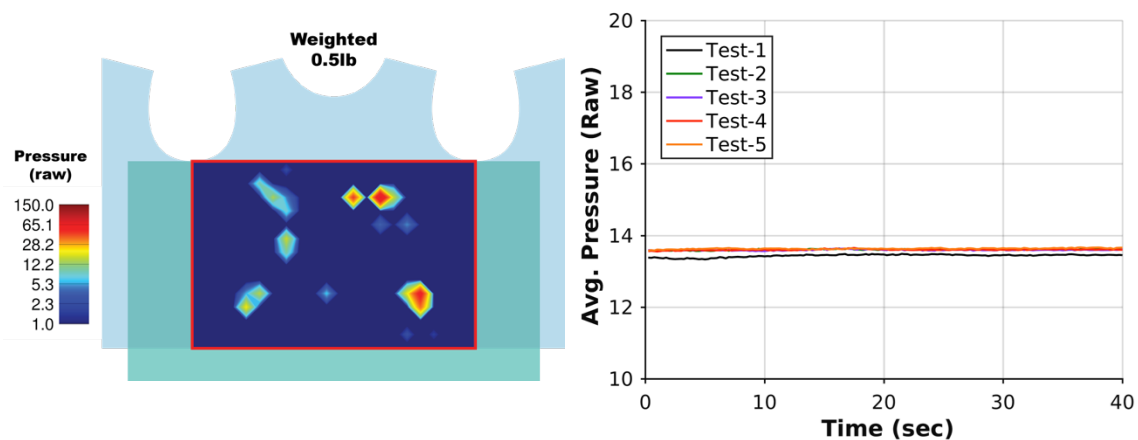


Figure 14: Average (between 5 tests) spatial raw* pressure distribution (left) and average pressure over time (right) for the weighted vest (0.5lbs). *Useful for relative comparisons and to understand special distributions, but not useful for determining absolute pressure levels

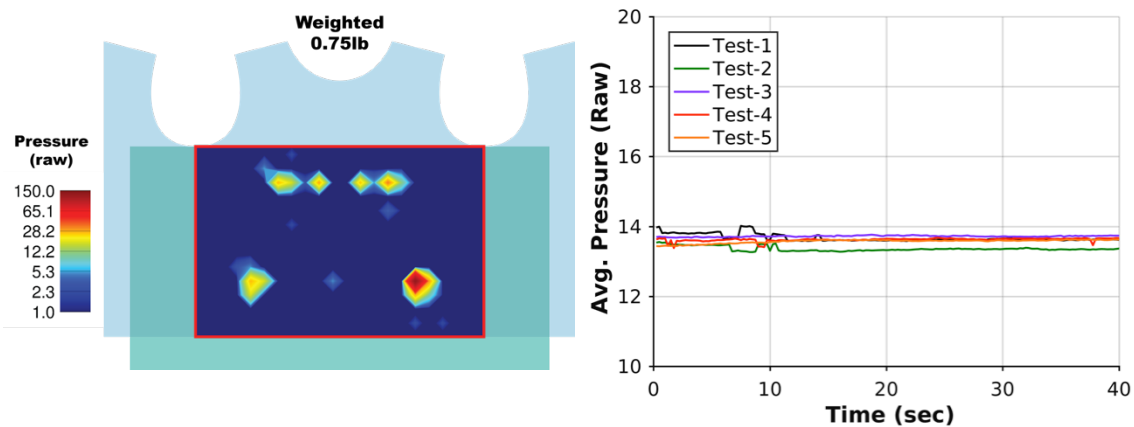


Figure 15: Average (between 5 tests) spatial raw* pressure distribution (left) and average pressure over time (right) for the weighted vest (0.75lbs). *Useful for relative comparisons and to understand special distributions, but not useful for determining absolute pressure levels

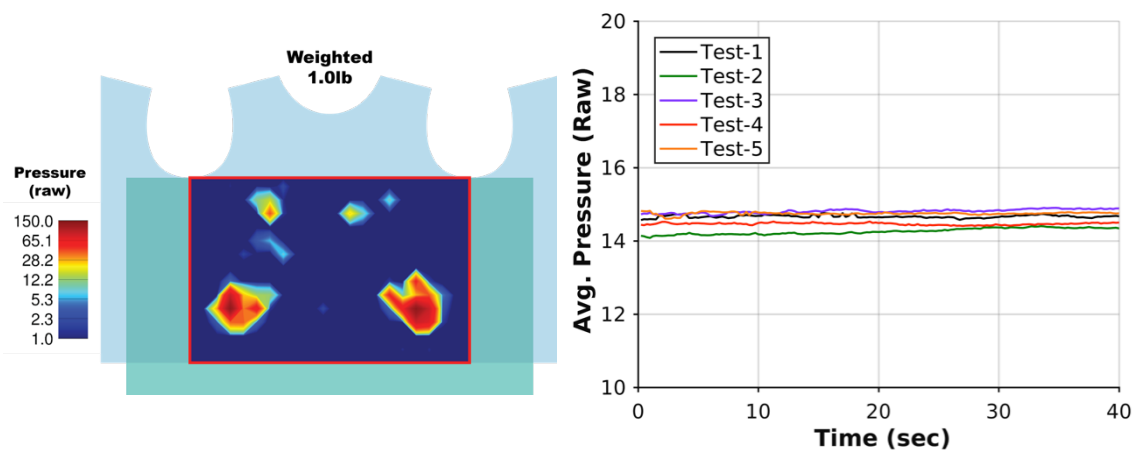


Figure 16: Average (between 5 tests) spatial raw* pressure distribution (left) and average pressure over time (right) for the weighted vest (1.0lb). *Useful for relative comparisons and to understand special distributions, but not useful for determining absolute pressure levels

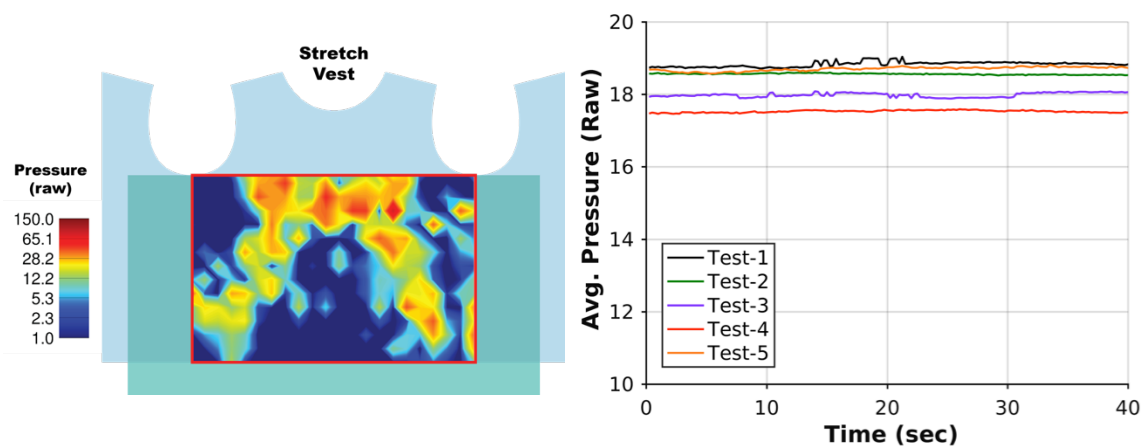


Figure 17: Average (between 5 tests) spatial raw* pressure distribution (left) and average pressure over time (right) for the stretch vest. *Useful for relative comparisons and to understand special distributions, but not useful for determining absolute pressure levels

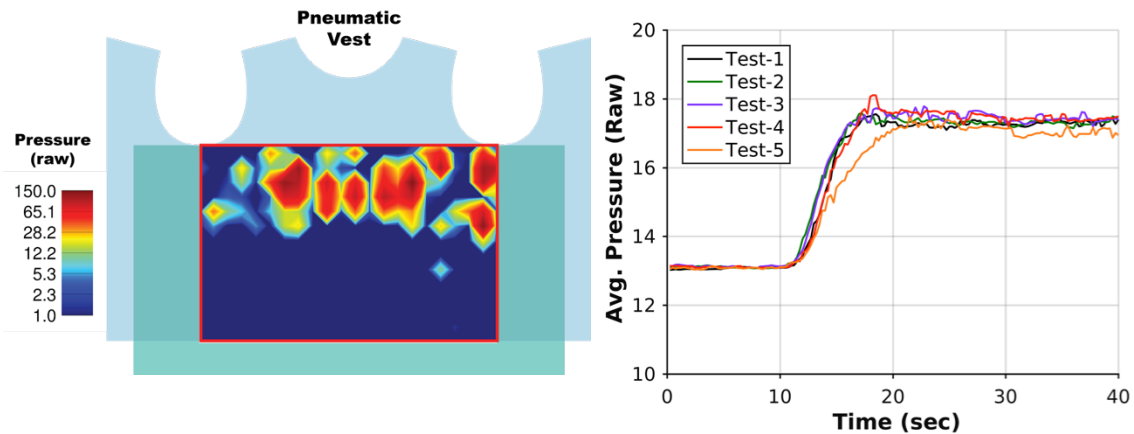


Figure 18: Average (between 5 tests) spatial raw* pressure distribution (left) and average pressure over time (right) for the pneumatic vest. *Useful for relative comparisons and to understand special distributions, but not useful for determining absolute pressure levels

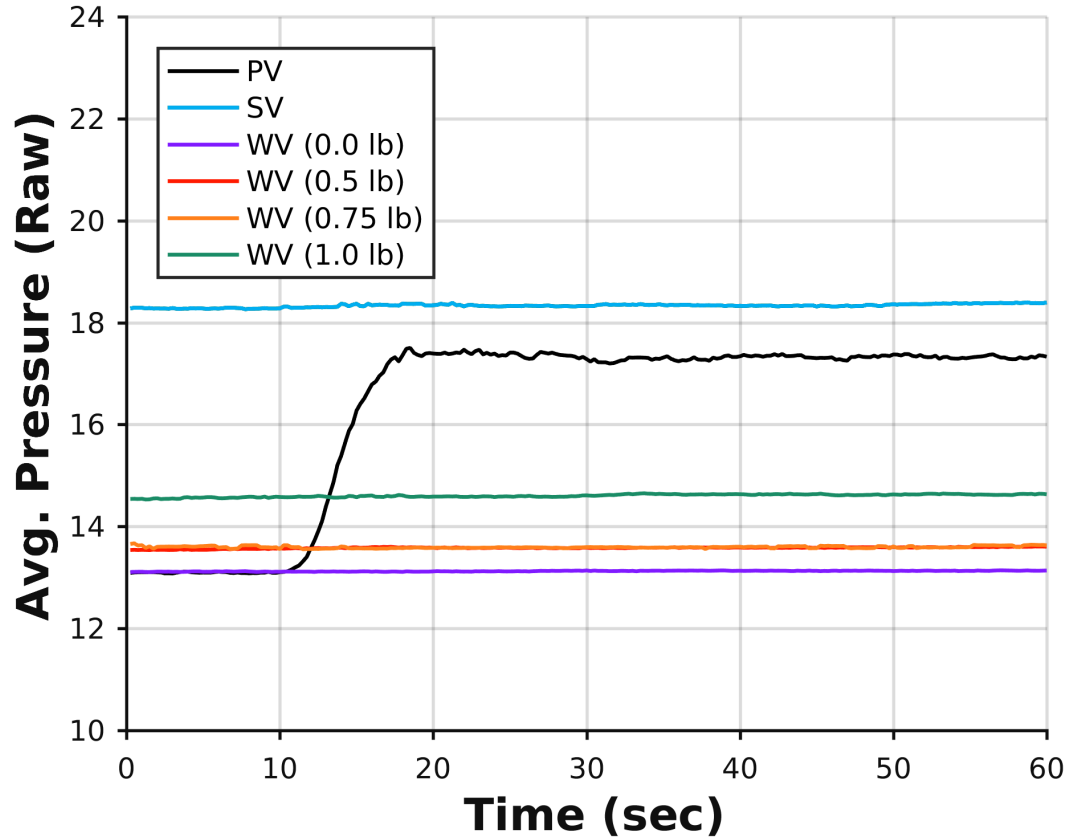


Figure 19: Average raw pressure over time for all three garments collected with the Tekscan sensor on the abdomen

FSR Shoulder Data

The average forces for each garment collected with the FSR for the shoulder are depicted in Table 5. The force data is displayed as a voltage. The stretch and pneumatic garments do not apply a detectable amount of pressure. The weighted garment has FSR voltage outputs of 0.00V (0lb), 1.83 (0.5lb), 3.12 (0.75lb), and 3.00 (1.0lb). According to the conversion provided by the sensor manufacturer (see Figure 12), this indicates that

the applied force is probably somewhere between 0.04lbs and 0.22lbs for the vest when the weights are inserted.

Table 5: Average raw voltage and corresponding forces (lbs) for each garment collected with the FSR sensor for the right shoulder

Garment	Mean Raw Sensor Output (V)	Force (lbs)	Variance (%)
Weighted – 0lbs	0.00	None	0.00
Weighted – 0.5lbs	1.83	~ 0.04	0.00
Weighted – 0.75lbs	3.12	~ 0.22	0.00
Weighted – 1.0lbs	3.00	~ 0.22	0.01
Stretch	0.00	None	0.00
Pneumatic	0.00	None	0.00

3.2.5 Discussion

3.2.5.a Distribution

The distribution of pressure varied per garment. The weighted vest applied a force to the shoulders, where the negative ease and pneumatic garments did not. The distribution of pressure over the abdomen also varied per garment. The weighted garment applied more focused pressures that increased as the weights increased, where the mannequin belly protruded, as seen in Figures 13-16. The stretch garment's pressure was the most evenly distributed over the torso of all the garments, as seen in Figure 17. The pneumatic garment had a more even distribution of pressure than the weighted vest. This pressure was concentrated higher up on the torso, in larger blob shapes, as seen in Figure 18. Having the pressure mat underneath the garments may have affected the distribution of pressure. This is a limitation that could be resolved in future testing by creating a more conformal and low-profile pressure measurement tool.

3.2.5.b Magnitude

Because of calibration limitations the exact magnitudes of pressure cannot be

reported, however the raw pressure magnitudes can be compared between garments. The negative ease stretch garment applied the highest average pressure (10.40 raw pressure units) and the pneumatic garment applied the second highest average pressure (8.95 raw pressure units). The weighted vest had lower average abdomen pressures, even with its heaviest weights (11lb) which applied an average of that 3.83 raw pressure units. The average pressure decreased as the weights decreased. The average pressure was calculated by averaging the total abdomen area. This can account for the low pressure applied by the weighted garment, since its pressure was very concentrated in certain areas. The pneumatic garment was the only garment able to provide a continuous range of pressures and able to provide a range of pressures while worn. The other garments are only capable of static pressure. The weighted garment is able to provide multiple pressures, but these are all in steps and can only be adjusted by doffing the garment and adjusting the weights then donning it again. The magnitudes of pressure vary between the different commercial products.

3.2.5.c Conclusion

All three garments are marketed and sold as DTP treatments for SPD, however the amount and distribution of pressure vary considerably per garment. This is consistent with the literature, (Morrison, 2007; Fristad, 2015) which points out the need for more standardized procedures and guidelines for the amount of pressure applied for the treatment of SPD. Our results suggest that the location and distribution of pressure in addition to the amount is also inconsistent between treatments options.

There are many unknowns and inconsistencies in DTP treatments. By developing an alternative system that is capable of applying repeatable pressure in different

locations, amounts, and for various durations, the optimal treatment could be systematically discovered. Additionally, through the literature and from OT feedback we know that treatment needs are very individualistic (UMN OTs; CSLL OTs; Olson & Moulton, 2004). A garment with a broad range of capabilities could meet this need by providing a customizable treatment for each individual with SPD.

3.3 DTP Garment Problem Variable Framework

Using feedback from therapy practitioners, guidelines from literature, and a functional clothing design process, a framework was created that identifies important variables for providing DTP therapy. Requirements and problems were identified and written down on post-it notes (color coordinated with the source of the requirement). These variables were then organized into categories in an iterative process. Ideally the framework would identify garment requirements, however many of the variables lack known values. Therefor the framework identifies the key problem variables for DTP garment design, many of which require further investigation. The proposed problem variables are visualized in the framework below and defined in the following table. Requirements pertaining to each variable, some of which require further investigation, are outlined in the table.

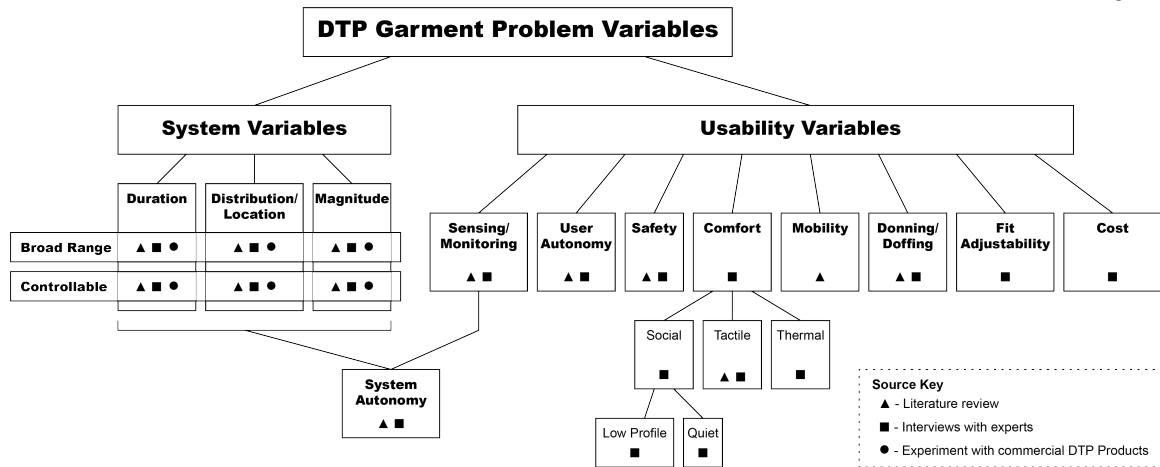


Figure 20: Problem variable framework. Variables are categorized as system and usability variables. The key indicates the source used to develop each requirement.

Table 6: DTP garment variables, definitions, and requirements

Variable		Definition	Requirement
System requirements	Duration	The length of time DTP is applied and the time between treatments	The garment is able to provide a controllable range of durations and times between treatments *requires further investigation
	Location	The areas where DTP is applied on the body	The garment is able to provide a controllable range of applied pressure areas *requires further investigation
	Magnitude	The amount of applied DTP	The garment is able to provide a controllable range of DTP applied to the body *requires further investigation

	Broad Range	A dynamic scope of possible values	The garment's duration, location and magnitude of pressure are capable of providing a range of values without removing the garment *requires further investigation
	Controllable	The ability to direct and regulate values	The garment's duration, location and magnitude of pressure can be adjusted without removing the garment *requires further investigation
Usability Requirements	Cost	The price the customer pays in order for users to access the treatment	Cost of the garment should not prohibit the user from access *Specific values should be determined
	Fit Adjustability	Ability to be custom tuned for users of different sizes and shapes and accommodate a growing child's size changes	The garment should accommodate a range of sizes, shapes and a growing child *Specific values should be determined
	Donning/ Doffing	Quick and stress free putting on and taking off of the garment	The garment accommodates quick and stress-free donning and doffing *Appropriate don/doff time should be investigated
	Mobility	The user's ability to travel from place to place and move their body without restriction	Does not restrict the user's ability to travel and move
	Comfort	The user's ability to wear the	Does not create user

		garment without social, tactile, or thermal irritation	social, tactile or thermal irritation
	Social	The user's ability to receive DTP therapy without drawing unwanted attention from other individuals or a group	Applying DTP does not draw unwanted attention or cause anxiety for the wearer in social situations (for instance, through an unobtrusive form factor or through creating noise)
	Tactile	Materials do not cause irritation to the wearer's skin	The garment does not irritate the wearer's skin. (e.g. through scratchy materials and through constricting neckline)
	Thermal	Does not overheat the wearer	Clo value should be reduced *specific values should be investigated.
	Safety	Does not cause harm to the wearer	The garment should not cause harm to the wearer
	User Autonomy	Allows user to control amount, location, and duration of pressure	The garment allows for user self-adjustment of pressure (e.g. location, duration, and magnitude)
	Sensing / Monitoring	A context aware system (i.e. is able to detect a need and measure response for expected outcomes)	The garment is able to measure needs and expected outcomes (e.g. GSR (Edelson et al., 1999), EDA (Chen et al., 2012), and HRV (Chen et al., 2012; Krauss, 1987))
	System Autonomy	A garment that is able to respond to sensed needs with the appropriate DTP response	The garment can provide has both sensing capabilities

		continuously	and actuation capabilities that can work together to provide DTP therapy as needed
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The systems variable branch of the framework encompasses the variables that are proposed to be essential for providing adequate DTP. These variables include a broad range and controllable duration, location and magnitude of applied pressure. The sources for these requirements come from the literature review (Chapter 2) and the quantitative and qualitative studies conducted for this thesis (Chapter 3). Through the review of literature, it has become evident that the optimal treatment parameters for pressure (i.e. location, duration and magnitude of applied pressure) for DTP therapy are unknown and not well understood (Reichow et al., 2009). The experts that were interviewed were also unsure of optimal treatment parameters. Additionally, through the evaluation of current DTP products, it became clear that each garment provided a different magnitude, duration and location of pressure as well as type of pressure. The optimal variables for pressure are not well understood, however these variables are key for providing compression therapy. A garment with a broad range of capabilities could be used to determine optimal parameters for DTP treatment. Additionally, the garment should be able to control the amount, location and duration of applied pressure in order to be used in the future to systematically determine optimal parameters.

Beyond understanding these parameters more clearly, it may also simply be necessary to provide a broad range of capabilities for the user. Pressure magnitude and location preferences may depend on the user, and may change depending on the time of

day or other factors (Krauss, 1987; Olson and Moulton, 2004; LouAnne Boyd). Some individuals may prefer constant or slowly changing pressure (Grandin, 1992) and gradual application or pressure may be less threatening for those with SPD (CSLL OTs). These are further reasons for a broad range of capabilities in a therapy garment. Further, habituation to pressure could lead to ineffective treatments (Olson and Moulton, 2004; UMN OTs). Pressure must be periodically removed or adjusted in order to avoid desensitization (Iggo and Muir, 1969), however this can be a difficulty when garments must be doffed. OTs have admitted to leaving the garments on during activities and transitions (Olson and Moulton, 2004), and the experts that were interviewed also voiced their concern that vests were “given out like candy” without concern for desensitization (UMN OTs). In order to meet all these needs, a DTP therapy garment should be able to dynamically adjust and alleviate pressure without doffing. This requires both a broad range of pressure (duration, location, and magnitude) and control of the pressure.

The second branch of the framework encompasses the proposed usability variables for a DTP garment. These are the variables beyond the bare essentials that help the user effectively, efficiently, and satisfactorily achieve compression therapy for sensory processing disorder.

Donning/Doffing: The usability variables branch includes easy donning and doffing of the garment. The OTs in Olson and Moulton’s study indicated that it was difficult to remove garments in the middle of an activity or during transitions (Olson and Moulton, 2004), additionally the experts that were interviewed also

expressed the importance and often difficulties of quickly putting on and taking off the garment (Patricia Orme; UMN OTs). A DTP garment should both be easy to don and doff and provide the option to alleviate pressure without doffing.

Mobility: Mobility is another requirement for effective treatment. Through the literature review it becomes evident that compression therapy aiming to lower anxiety and arousal levels is more effective when applied if the user has higher initial anxiety or arousal levels (Edelson et al., 1999). Non-wearable DTP products make need-based therapies more difficult because the user typically is required to travel to the compression device, often by appointment (Edelson et al., 1999). DTP products should not restrict user mobility and should allow for the treatment to travel with the user so it can be used when needed.

Comfort: Comfort is a multidimensional usability requirement. Several aspects of user comfort are identified in the framework, including social comfort (requiring a low profile and quiet device), tactile comfort, and thermal comfort. The garment should not cause any unwanted social attention due to a bulky form factor or loud noises when applying pressure. Patricia Orme, an expert that was interviewed indicated that children start to care what the garments look like starting in middle school. The OTs also indicated that the garments shouldn't irritate the wearer's by being too close to the neck or through protruding seams and scratchy materials. Finally, it is important that the garments are not uncomfortably hot for the wearers (OTs). The clo value, a measure of the ability of insulation to provide warmth (Watkins & Dunne, 2015), of the garment should be reduced.

Safety: User safety is always a critical requirement for any designed object or system. OTs in Olson and Moulton's study voiced their concern that weights might lead to biomechanical stress for the wearer (Olson and Moulton, 2004). The garment should not cause any harm to the wearer or compromise the user's safety in any way.

User Autonomy: Another important variable is user autonomy. The wearer should be able to have control over the amount, duration and location of applied pressure (Grandin, 1992). DTP garments should be designed to accommodate this need.

Sensing / Monitoring: The garment should be able to sense / monitor for both need recognition and evaluation of treatment. As mentioned above, treatment is more effective for those with higher initial arousal or anxiety levels (Edelson et al., 1999). However, children with ASD are often unable to communicate deep pressure's effect on anxiety and arousal (Edelson et al., 1999). Additionally, OTs have voiced their concerns that treatments are not being used properly at home (Olson and Moulton, 2004; CSLL OTs). Providing the ability to detect arousal and/or anxiety level and evaluate the change in arousal and/or anxiety, paired with a system that could respond accordingly, could help solve these problems. Integrated sensors could also help with the evaluation of treatments in order to determine optimal protocol and answer many of the unknowns about DTP therapy. Potential ways to monitor anxiety and arousal level include electrodermal activity (EDA) and heart rate variability (HRV) (Chen et al., 2012; Krauss, 1987).

Cost: Occupational therapists (CSLL OTs) discussed the importance of providing a treatment that was monetarily accessible for users. The cost of the garment should not restrict access to the treatment. This requirement requires further investigation in order to determine specific criteria for the garment.

Fit Adjustability: Another requirement identified by the CSLL OTs was fit adjustability. In order to accommodate a child that is growing and also using one garment for several different children that are different sizes requires adjustability. This requirement would also help to provide a more accessible treatment.

System Autonomy does not fall under either the system or usability variables because it encompasses both branch aspects. In order to have an autonomous system both sensing capabilities as well as controllable and dynamic actuation are required. With an autonomous system treatment can be aware of the context, identify a need, respond and finally evaluate the user response. This could be extremely beneficial for individual users and additionally in order to help answer questions about optimal treatment parameters.

3.4 Requirement Evaluation of Existing DTP Products

The following sections uses the problem variable framework to evaluate the different DTP garments (weighted, stretch and pneumatic) that were tested in Chapter 3. Each garment has its own shortcomings.

The weighted garment meets only one system variable requirement and two usability variable requirements. The garment is able to accommodate a broad range of

pressure duration, but can only apply pressure to limited locations (shoulders and upper chest). The magnitude of pressure is adjustable in limited steps (based on weights provide), but the garment must be removed and weights removed and replaced in order to achieve a different level of pressure. The weighted vest is relatively easy to don and doff with a center front zipper. The garment also has adjustable side Velcro tabs to accommodate different sizes. There are several usability requirements that the garment could meet, but require further work. The vest is somewhat affordable, but still costs more than \$100 USD. The garment does not incorporate sensors, but could in the future. The garment provides some user autonomy, in that it can be unzipped and doffed if it irritates the wearer. However, finer tuning of pressure cannot be controlled by the wearer. Some user comfort needs are met, while others require work. The garment sits away from the user's neck and does not have and scratchy seams, therefor meeting the tactile requirements. The garment makes no noise, but is bulky, so it meets half of the social requirements. Finally, the weighted vest was indicated by OTs to be somewhat hot in the summer, so may not fully meet the thermal comfort requirement. Further investigation should be done to understand thermal comfort. Usability requirements that were not met were safety and mobility. Weighted vests were indicated to potentially cause biomechanical stress on the wearer's body (Olson & Moulton, 2004). This has not yet been tested. The vest does not meet the requirement for mobility because, according to the manual, the vest should only be worn when sitting. Because the weighted vest does not yet incorporate sensing and does not have full actuation capabilities, it does not meet the system autonomy requirement.

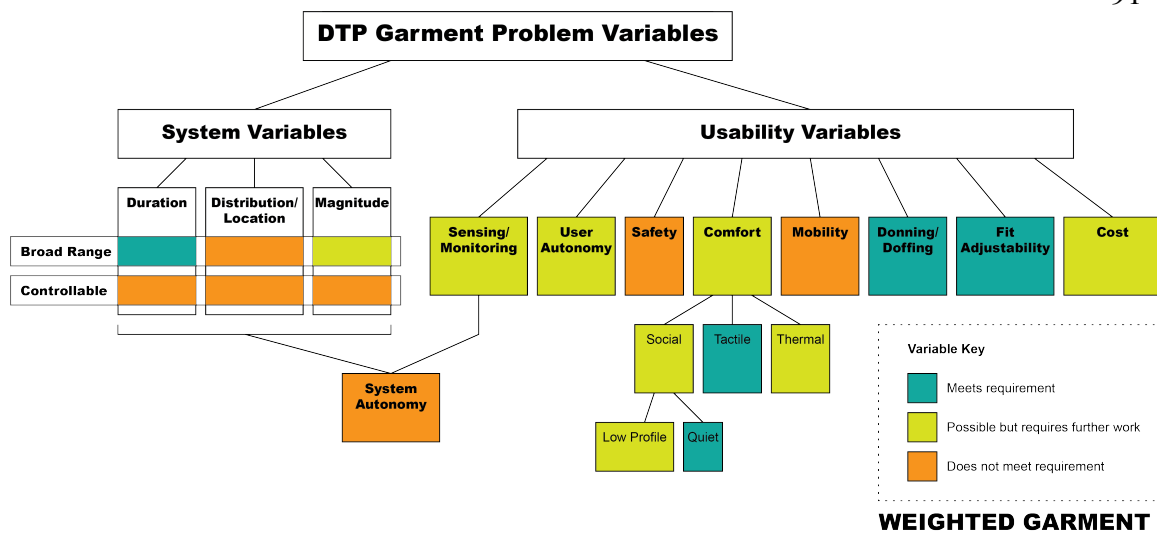


Figure 21: Weighted garment requirement evaluation

The stretch garment meets one system requirement and three usability requirements. It is capable of a broad range of pressure durations, but is not able to apply different magnitudes or locations of pressure and has no control capabilities and cannot easily support control of these variables. The garment does not harm the wearer, allows for user mobility and has fit adjustability capabilities (hook and loop tape). The stretch garment could incorporate sensing capabilities in the future, but cannot accommodate an autonomous system because of its non-existent actuation capabilities. The garment is somewhat expensive, but still affordable. The garment does not provide user autonomy, because pressure cannot be adjusted by the wearer. Additionally, the garment is a struggle to don and doff and the wearer requires assistance to don the garment. This process is both difficult and time consuming. The garment meets many of the user's comfort needs, including a low-profile form factor and no noise system. It also has limited seams and sits away from the neck, therefor meeting the tactile comfort needs. The garment may be hot for the wearer during summer months. Overall the stretch

garment does a fair job meeting most of the usability needs, beyond user autonomy and easy donning and doffing. However, the stretch garment does not meet any system needs beyond providing a broad range of (non-controllable) possible pressure durations.

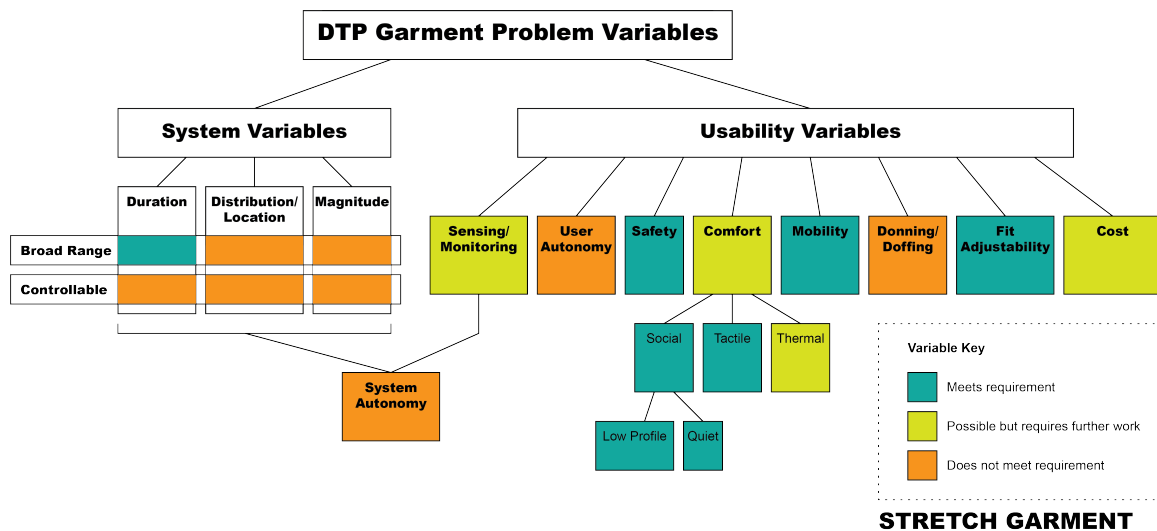


Figure 22: Stretch garment requirement evaluation

The pneumatic garment meets, or is able to meet in the future, the most requirements of the three products. It is capable of a broad range of durations and magnitudes of pressure as well as some limited location variability in some models. These all have the potential to be controllable, and for now are controlled by a hand pump. The system can accommodate user autonomy, is safe, allows for user mobility, is easily donned and doffed and accommodates various sizes with side hook and loop tabs. The garment could integrate sensing capabilities in the future allowing for an autonomous system. The garment's shortcomings are that it is bulky and loud when inflated, and that it requires a hand pump to inflate. The garment may also be hot for the wearer and is expensive.

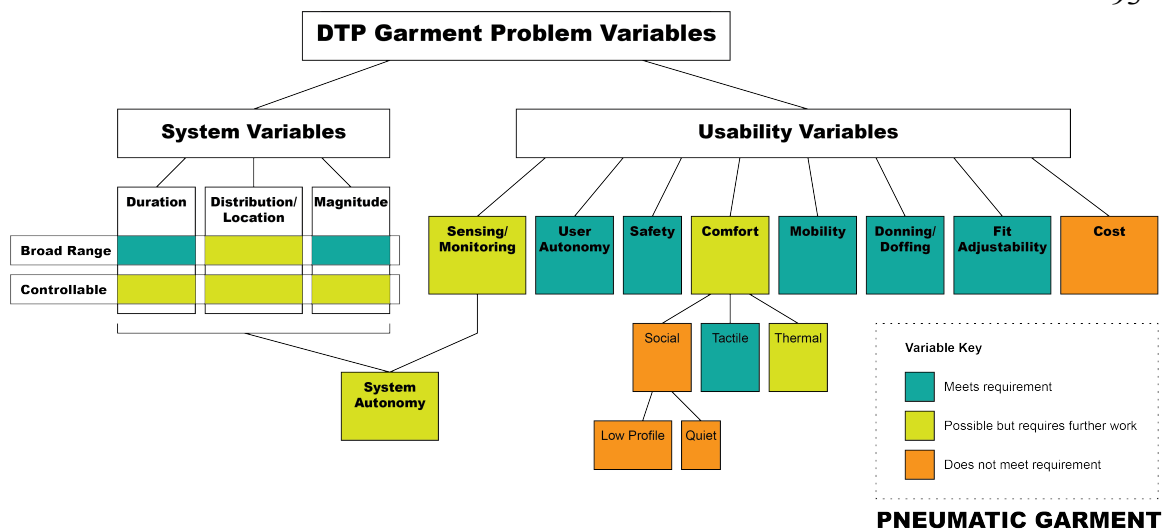


Figure 23: Pneumatic garment requirement evaluation

None of the three existing DTP products are able to meet all requirements proposed in the problem variable framework. Namely, the garments are unable to be both dynamic, controllable and unobtrusive for the wearer. Providing a controllable range of pressure durations, locations, and magnitudes is key both to meet various user needs and also in order to determine optimal treatments. None of the commercial products are able to provide these key requirements. The Pneumatic garment is the closest able to meet these system variable requirements, however, the garment is bulky and noisy when inflated, which could create social stress for the wearer. A DTP garment is needed that can meet all system variables without creating social discomfort.

CHAPTER 4. TECHNOLOGY DEVELOPMENT

A literature review (Ch. 2) and qualitative and quantitative studies (Ch. 3) culminate in a requirement framework that indicates that dynamic pressure duration, location and magnitude while remaining wearable and unobtrusive are important for providing DTP

therapy, but current products fall far short of meeting these requirements. In this chapter, an innovative system is developed to better serve the needs of those who use DTP therapy. The approach adapts previously described SMA technology to create a novel, unobtrusive, dynamically controllable vest.

4.1 SMAs

As introduced in Chapter 1, SMAs, such as NiTi, are a category of active materials that undergo solid-state phase transformation as they are heated (transforming from low-temperature, malleable martensite phase to high temperature, superelastic austenite phase). This phase transformation manifests as a repeatable, macro-scale change in shape in the absence of external stress that can be tailored via preprocessing and annealing of raw SMA material (Madden et al., 2004). Forming SMA wire into low spring index (spring diameter / wire diameter ~ 3) springs — and preprogramming the material such that the memory state is the solid spring (i.e., fully shortened) form — enables repeatable linear actuation strokes capable of producing large ($>5\text{N}$) forces and large ($>75\%$ reduction in length) displacements in a highly compact ($\sim 1\text{mm}$ diameter spring) form factor (Seok et al., 2013).

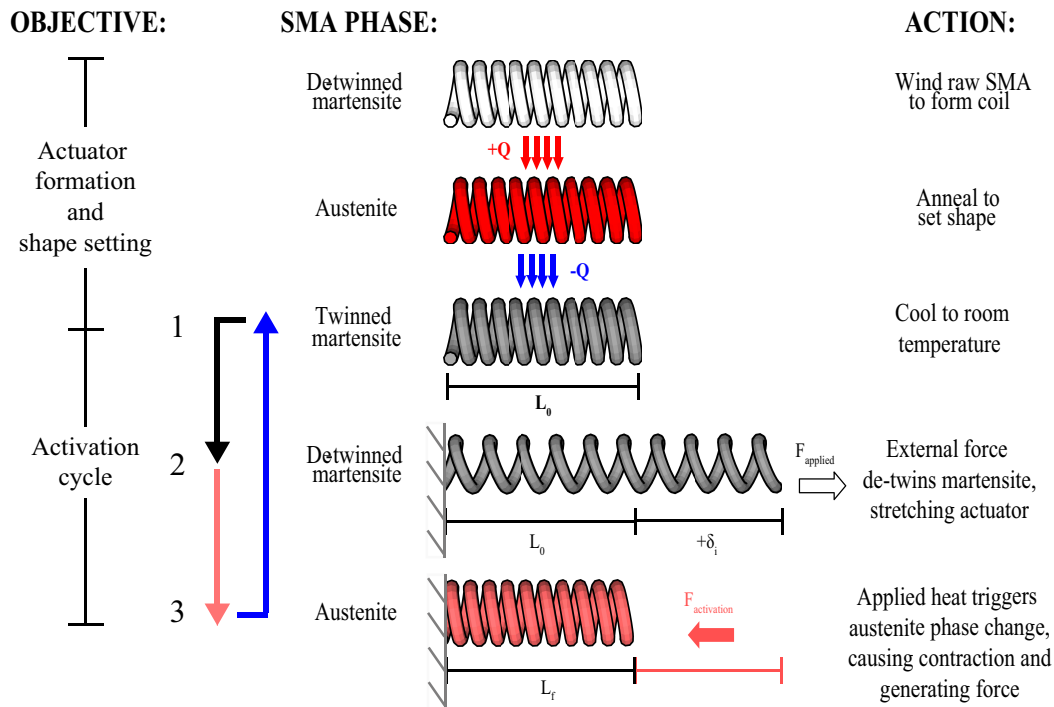


Figure 24: NiTi wire is wound into springs and then annealed to set their shape and form the actuators. After annealing, the actuators will return to their austenite state when heated. An external force can extend the twinned martensite SMA spring actuators, forming their de-twinned martensite state. The actuators will contract again when heated forming their austenite phase.

(B. Holschuh, Obropta, & Newman, 2015)

By integrating SMA springs into the circumference of a garment, the SMA actuation stroke can be exploited to generate increasing amounts of hoop stress in the garment as the SMAs contract (stretching the garment fabric), which causes an increase in pressure if wrapped around an object (or person). As the number of springs increases, so does the total potential pulling force, and thus the total potential hoop stress and active pressure. Because these actuators trigger as they are heated, they can be effectively controlled through an applied current (which induces Joule heating in the material). Additionally, by changing the magnitude of the applied current the amount of pressure generated can be modulated (Holschuh and Newman, 2016). As a result, SMA-based

compression garments can be highly functional (i.e., creating counter-pressures > 225 mmHg), unobtrusive, silent, and remotely controllable (if paired with onboard batteries and a wireless controller), with great potential for applications such as treating SPD (B. Holschuh, Obropta, & Newman, 2015; Holschuh and Newman, 2016; Duvall et al., 2016).

4.2 Shape Memory Alloy Activated Compression Garment (SMA-CG) Design

The physical garment was designed in a two-layer system, inner comfort layer and muscle (actuation) layer, which creates the compression needed to generate DTP. An outer protective and aesthetic layer was also developed for a different version of the garment not tested for this thesis. The muscle layer is made from a combination of passive fabric and 16 SMA spring actuators. The inner comfort layer insulates the wearer from SMAs (as they are heated during actuation) and creates a low friction base on top of which the muscle layer moves. This was created by combining a lycra textile, for low friction and comfort, sewn with an aramid neoprene textile for insulation and heat resistance. The muscle layer uses a combination of non-stretch, low friction textile, and SMA spring actuators in a laced formation on the left and right sides of the torso. The SMAs were attached to the textile using sew-on metal hooks. This area is structured and reinforced with boning, which helps to evenly distribute pressure generated by the SMAs. A zipper was added, allowing for easy donning and doffing of the garment.

To create the actuation regions, on each side of the garment a singular SMA spring (1.25 mm diameter, 53.3 cm length when fully extended) was laced 8 times from bottom to top of the garment, spaced 1.9 cm (0.75 in) apart vertically with a gap of 5.1 cm (2 in)

horizontally. This architecture was repeated on each side of the garment, creating two actuation regions each with 8 parallel actuators evenly spaced (for a total of 16 actuators). These springs acted as electrical resistors (that heat when exposed to current), and each spring comprised an independent circuit capable of producing compression when powered. The SMA-CGs can be activated using Bluetooth LE and an app on a mobile device for unobtrusive remote control (Duvall, Dunne, Schleif, & Holschuh, 2016)). Remote control was not integrated in the version of the garment tested for this thesis.

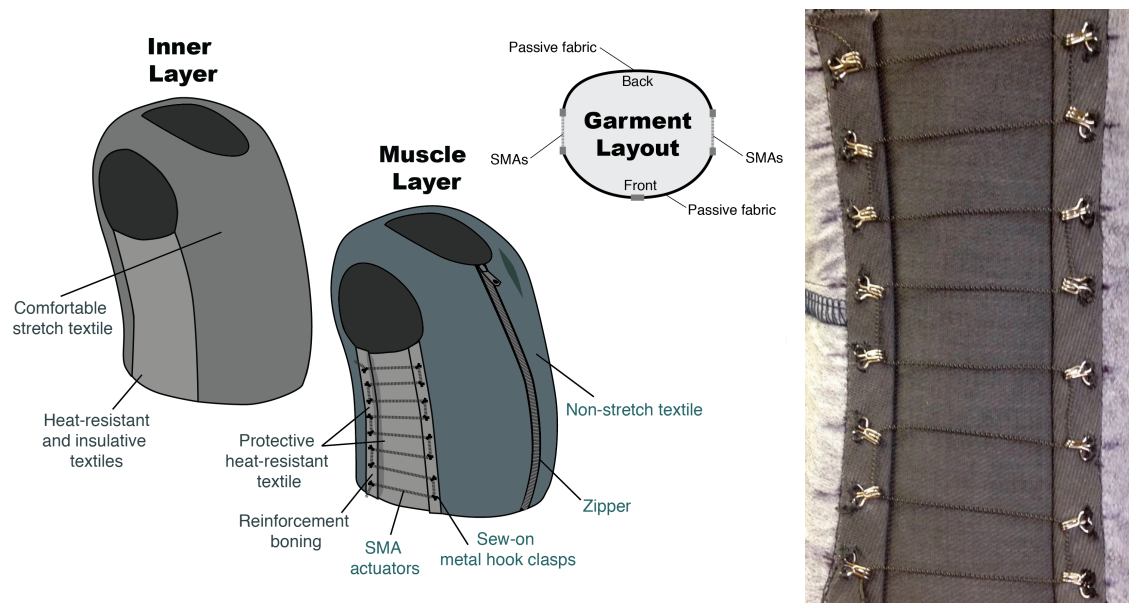


Figure 25: Shape memory alloy activated compression garment. The garment has three layers (left): an inner layer for comfort and insulation, a muscle layer that performs the hug, and an outer aesthetic and protective layer. The SMA springs (right) contract when a current is applied, creating the compression needed for DTP therapy.



Figure 26: Front and 3/4 view of the SMA-CG prototype.

4.3 Active Pressure Modeling

Previous work by Holschuh and Newman has shown it is possible to predict the pressure generated by an active garment with integrated SMA actuators, based on 12 system parameters (Holschuh & Newman, 2015). Specifically, active pressure can be calculated as follows (see Table 8 for detailed breakdown and description of model parameters):

$$P_A = \frac{\Delta X_{System} G_A d^2 n_a E t}{r(G_A d^2 n_a L_{F0} + 8 E w t C^3 \eta L_{S0})}.$$

This pressure production model is based on several assumptions, which affect the overall accuracy of its predictive power (Holschuh et al., 2016). These assumptions include:

1. Pressure is generated on a rigid, cylindrical object

2. Friction is negligible and garment is structurally uniform (i.e., tension is generated uniformly around the circumference)
3. SMA and passive fabric have linear stress-strain behavior (i.e., can be modeled as linear springs)
4. SMAs are fully transformed (i.e., model only predicts **maximum** possible pressure generated)

Holschuh et al. have shown SMA actuators have been shown to be highly linear (2015), and the passive fabric selected for the DTP vest prototype (a satin weave textile reinforced with fusible interfacing) was tested using an Instron tensile test apparatus and shown to also be highly linear ($R^2 > 0.95$) for strains up to 6%. These properties conform well to model assumptions. Friction properties, garment structure, and mannequin geometry are more difficult parameters to control (and in reality, will necessarily deviate from the idealized model assumptions). Deviations in these assumptions will affect model accuracy.

In order to model the DTP vest system developed in this study, values for each of the 12 system parameters (Holschuh and Newman, 2015) were estimated from a variety of sources, or measured directly (enumerated in Table 8). Specifically, values were sourced in one of the following ways:

Table 7: Modeling value sources

Source	Value
(1) Known a priori from SMA actuator manufacturing process	SMA spring index (C)
	SMA wire diameter (d)
(2) Experimentally determined specifically for DTP vest	Passive fabric Young's Modulus (E)

prototype	1. Fabric un-stretched length (L_{F0})
	2. SMA twinned-martensite length (L_{S0})
	3. Number of parallel actuators (n_a)
	Average object radius (r)
	Fabric thickness (t)
	Fabric width (w)
(3) Cited from previous experiments / literature	SMA austenite shear modulus (G_A), and
	SMA spring packing density (η)
(4) Calculated / derived from other parameters	4. Un-stretched system closure gap (ΔX_{System})

Based on the estimated system parameters, the active pressure model predicts the DTP prototype system will generate a maximum of **7.01 kPa [52.5 mmHg]**. Optimum DTP metrics still need to be established, however other clinical compression garment metrics find the predicted measure of 52.5 mmHg to be within (or above) acceptable range: Teng and Chou experimentally measured burn compression garments and found them to vary between 20-40 mmHg (Teng & Chou, 2006), and Brennan et al. quotes elastic garments between 30-60 mmHg (Brennan & Miller, 1998). Since these applications of compressive garments are more tolerant of patient discomfort and mobility restriction (both of which have been reported at these levels of compression), it is likely that a benchmark for DPT would be lower than that of burn recovery or other circulatory conditions. Based on these

metrics the SMA garment system should produce the required pressure output for DPT treatment.

Table 8: Analytical pressure production model inputs and outputs

Source	Parameter	Description	DTP Vest Value	Units
Manuf. Specification	C	SMA spring index (D/d)	3	–
	d	SMA wire diameter	3.05×10^{-4}	m
Cited from literature	η	SMA spring packing density	0.9	–
	G_A	SMA austenite shear modulus	7.5×10^9	Pa
Experimentally determined	E	Passive Fabric Young's Modulus	1.29×10^7	Pa
	L_{F0}	Passive Fabric's unstretched length	0.434	m
	L_{S0}	SMA twinned martensite length	0.0127	m
	n_a	Number of parallel actuators in the system	16	–
	r	Object radius (assuming cylinder)	0.088	m
	t	Passive fabric thickness	0.00027	m
	w	Passive fabric axial width (i.e., garment height)	0.17	m
Calculated	ΔX_{System}	Unstretched system closure gap = $[2\pi r - (\text{other non-fabric structures}) - (L_{F0} + L_{S0})]$	0.10 [7 mm zipper]	m
	P_A	Active counter-pressure	7.01 [52.5 mmHg]	kPa

4.4 SMA Power, Length and Time

Because the ultimate objective of this research effort is to assess the feasibility of SMA-based compression systems to provide dynamic compression for DTP applications, the relationship between SMA spring length, applied power, and actuation time first needs to be better understood to establish the feasible limits in terms of cycle time and power consumption. Several SMA actuators were manufactured using custom equipment

at the UMN Wearable Technology Laboratory for both performance characterization / validation testing and prototype creation. Length-voltage-time tests were conducted to assess response time as a function of length and applied power. In each test, a predetermined voltage was applied to an extended (i.e., de-twinned) actuator of a given length, and response time (measured in seconds to complete total constriction) was measured. Each test condition was repeated three times. The results are shown in Figure 27.

The results of this test are consistent with expectations: as actuator length increases, response times are slower for a fixed voltage. Beyond a critical length (which varies for a fixed power input), response times slow non-linearly (trending to zero response – or infinite response time), suggesting that beyond a certain threshold the applied power is insufficient to induce heating above the critical SMA activation temperatures. Data is represented with ± 1 SD error bars in both the X and Y axis, when available. Deviation in actuation time tends to increase with SMA length (due to increasing heat transfer variance). These findings point toward a reduction in system actuator use in order to reduce actuation time and power consumption. Alternatively, larger power use could also achieve the desired actuation time if a longer length of SMA spring is required.

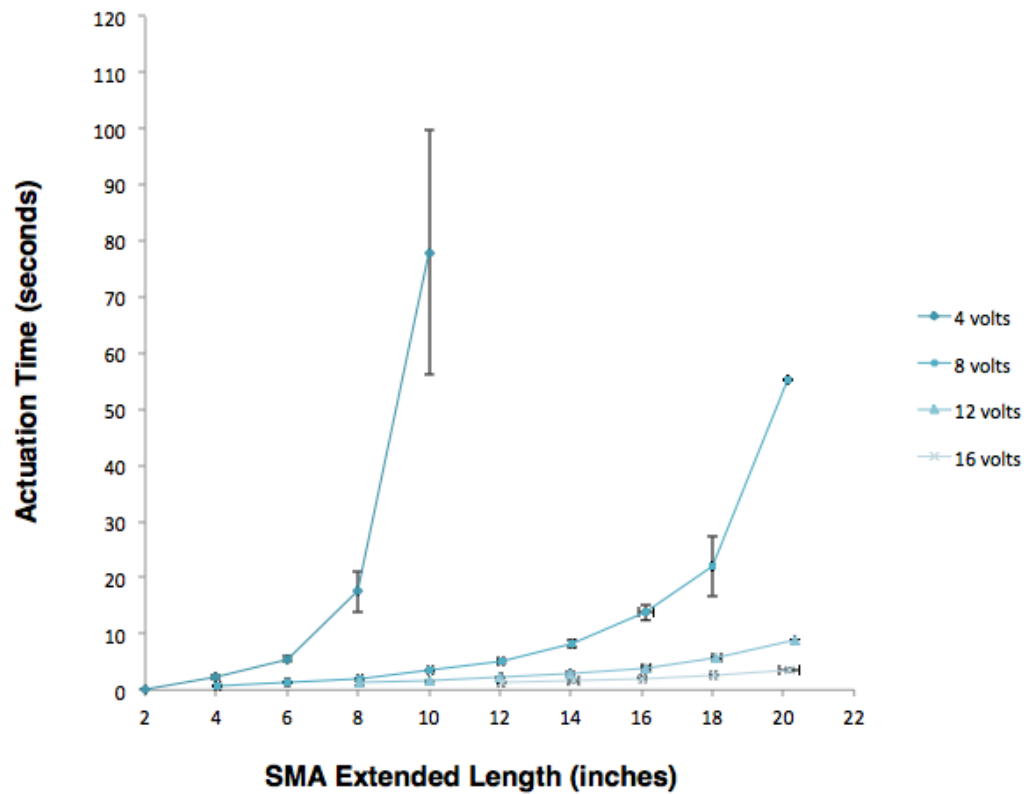


Figure 27: Depicts SMA actuator power, length and time plot.

4.5 Experiment Design

The sensor mats and calibration method used to collect the data for the SMA-CG are different than the methods in this thesis used to collect pressure data for current DTP products available on the market due to limitations in sensor availability. Because of this, data cannot be accurately compared between the two tests.

To characterize the pressure generation capabilities of the active DTP vest system, the vest was donned on a 3T child-sized mannequin and pressure data was collected as a function of spatial location and time for a variety of power inputs. To collect the pressure

data, a Tekscan CONFORMat 5330 pressure sensor (471 mm x 471 mm active sensing region, 1024 sensing elements, 0.5 sensels / cm², 34 kPa maximum pressure) was centered on the mannequin (underneath the vest system) and secured using adhesive tape. Although the sensor was one of the more 3D-conformable methods available for collecting surface pressure measurements, conforming a planar measurement device to the topography of the body was a challenge. Because of sensor constraints such as overlaps, wrinkles, and the exacerbation of these factors in body areas with more extreme curvature (such as, in the case of the mannequin used in this test, the more extreme concavity at the lower back), data was collected only on the front and sides of the garment. The area falling within the front and sides of the garment (as shown in two dimensions in Figure 28) contained 11 x 25 sensors (for a total of 275 data points). For each time instant, the pressure measured by each sensor in the array was captured, and the average pressure across the entire array was calculated.

A baseline pressure measurement was collected from the mannequin-mounted sensor before the garment was donned, and this bias was removed from the garment pressure data. The garment was then donned on top of the Tekscan sensor and fastened, as it would be worn on the body. All data was collected without repositioning the sensor or the garment after this initial donning procedure.

The test procedure characterized the SMA DTP vest at various power inputs in order to determine pressure output. In each of 5 successive trials, data was collected for 30 seconds at a 0V, then power was applied for 5 minutes each at 10V, 15V, and 20V increments, then power was shut off and the vest was allowed to cool down. Voltage was

adjusted manually at each time interval. Current (A) was recorded at each power level for each test in order to calculate total power (W). To determine nominal pressure for each power step, the average pressure for each sensor in the array was calculated for the last 60 seconds of activation for all five samples. Then the average of these samples was calculated. The average standard deviation was calculated spatially.

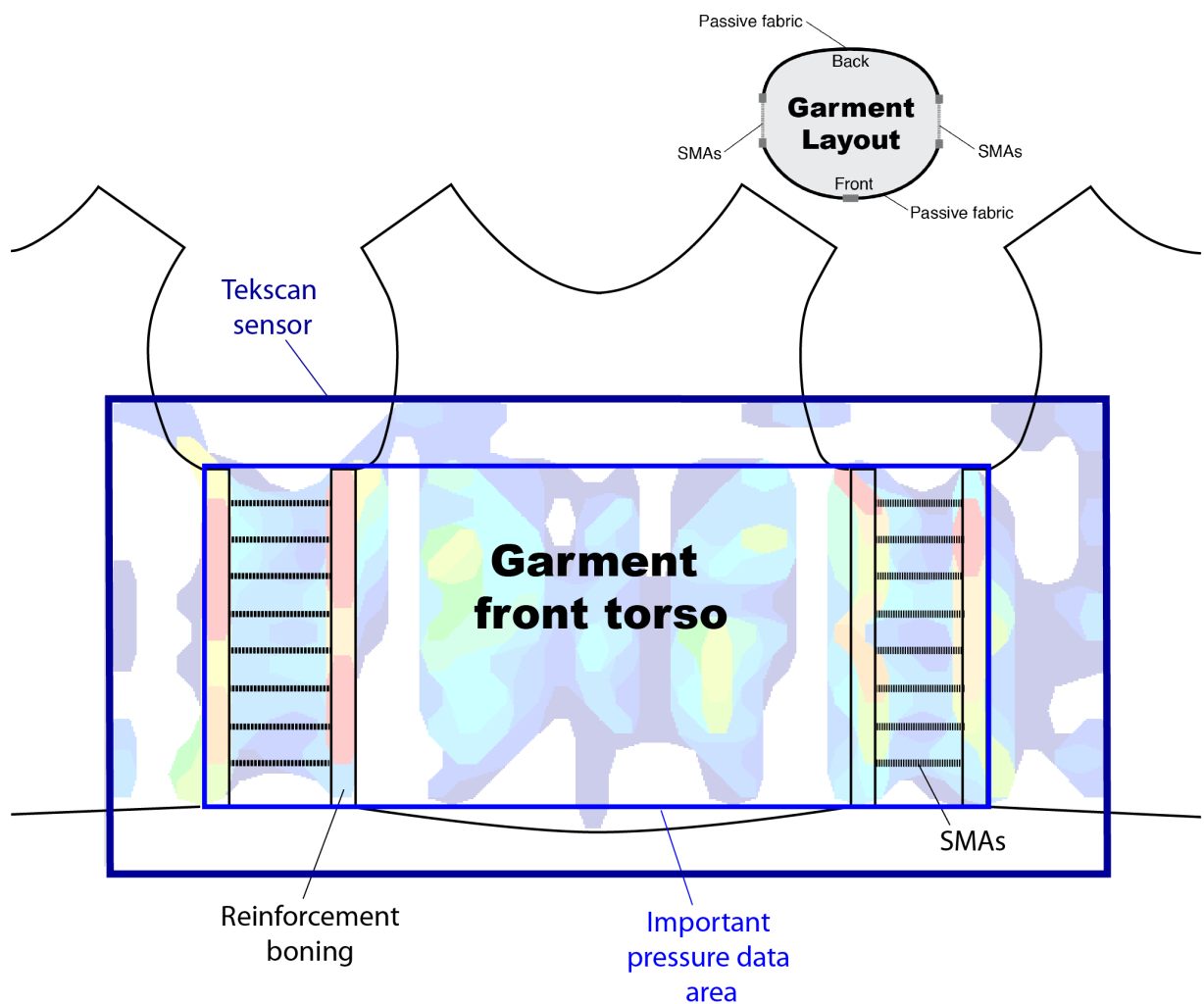


Figure 28: Tekscan Inc. CONFORMat sensor and garment placement for data collection.

4.6 Results

Figure 29 presents the average of the pressures measured by all sensors in the recorded window for each time sample in each of the five successive trials (separate trials shown in differing colors). The callout images show representative samples of the pressure distribution throughout the array for each power step in the test procedure. As expected, as power increases so does the average pressure output for all 5 tests. When power is removed, pressure decays to initial values as the garment cools.

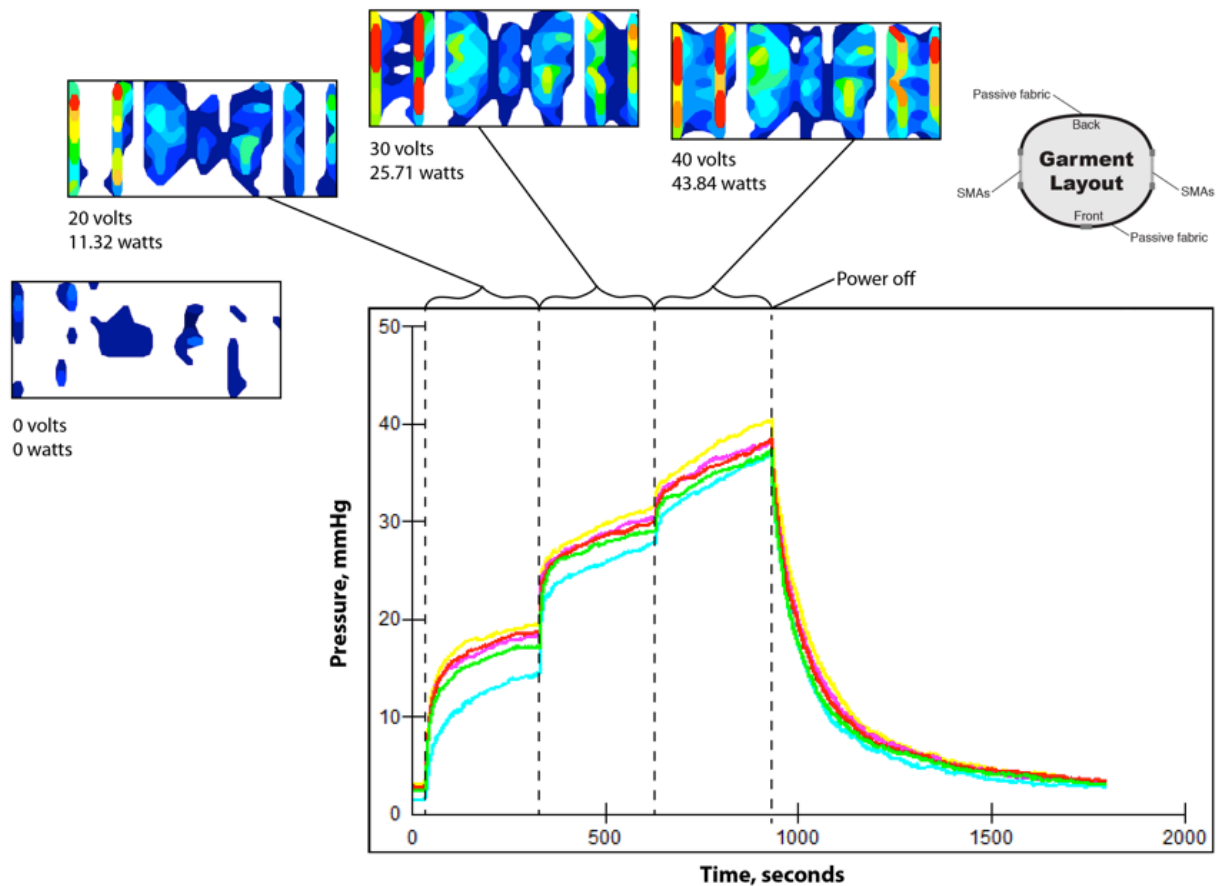


Figure 29: Data showing average pressure, mmHg, over time. Average pressure is defined as the average force applied over an area. Power was applied with increased intensity at various intervals (30 second, 5 minutes and 30 seconds, 10 minutes and 30 seconds, and 15 minutes and 30 seconds.) Power was shut off after 20 minutes and 30 seconds. Data shows that the average pressure output increased with power input.

Figure 30 illustrates the difference in pressure measured by the CONFORMat sensor array when the vest is powered off (when the body experiences only the force of the passive garment) and at full power (when the body experiences the force generated by the SMA actuators powered at 40 volts). Spatial distribution of pressure in these two conditions is also illustrated. Garment structures (e.g., SMA actuators, boning, etc.) are visible in the pressure distribution, as they create local non-uniformities in the pressure field.

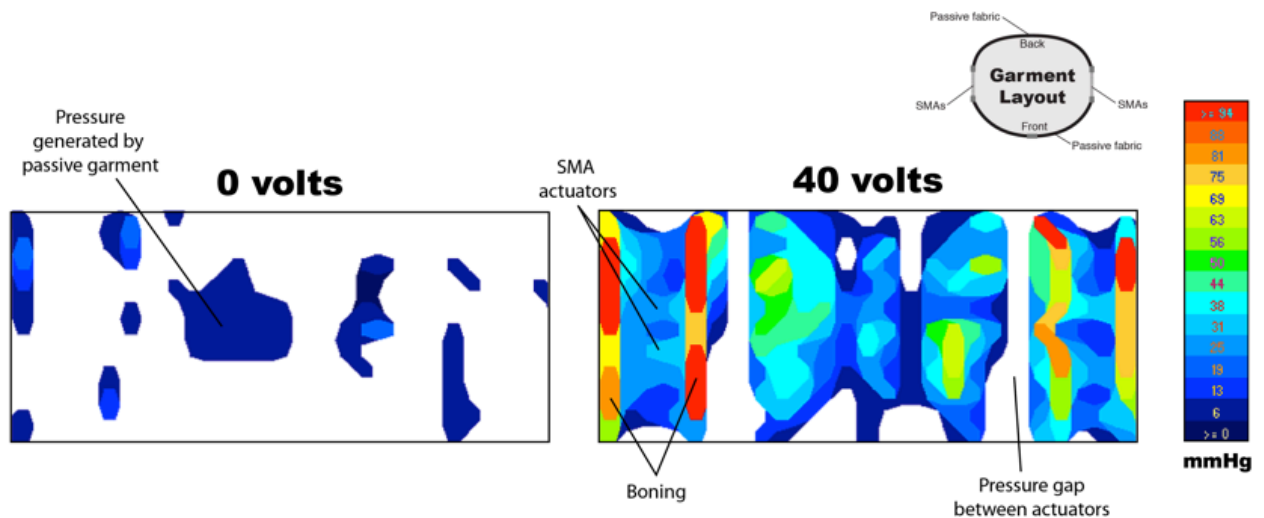


Figure 30: Pressure map comparing output with no applied power and at max power. The temperature bar corresponds to pressure measures in mmHg depicted in the pressure map.

Figure 31 presents average pressure generated by the garment as a function of applied power. As power increases, so does average pressure generated, to a maximum of 37.6 mmHg at 43.8 W. The maximum predicted pressure based on the validated SMA garment model (52.5 mmHg), is also presented – the prototype garment generated 71.6% of maximum predicted pressure at the highest power setting tested.

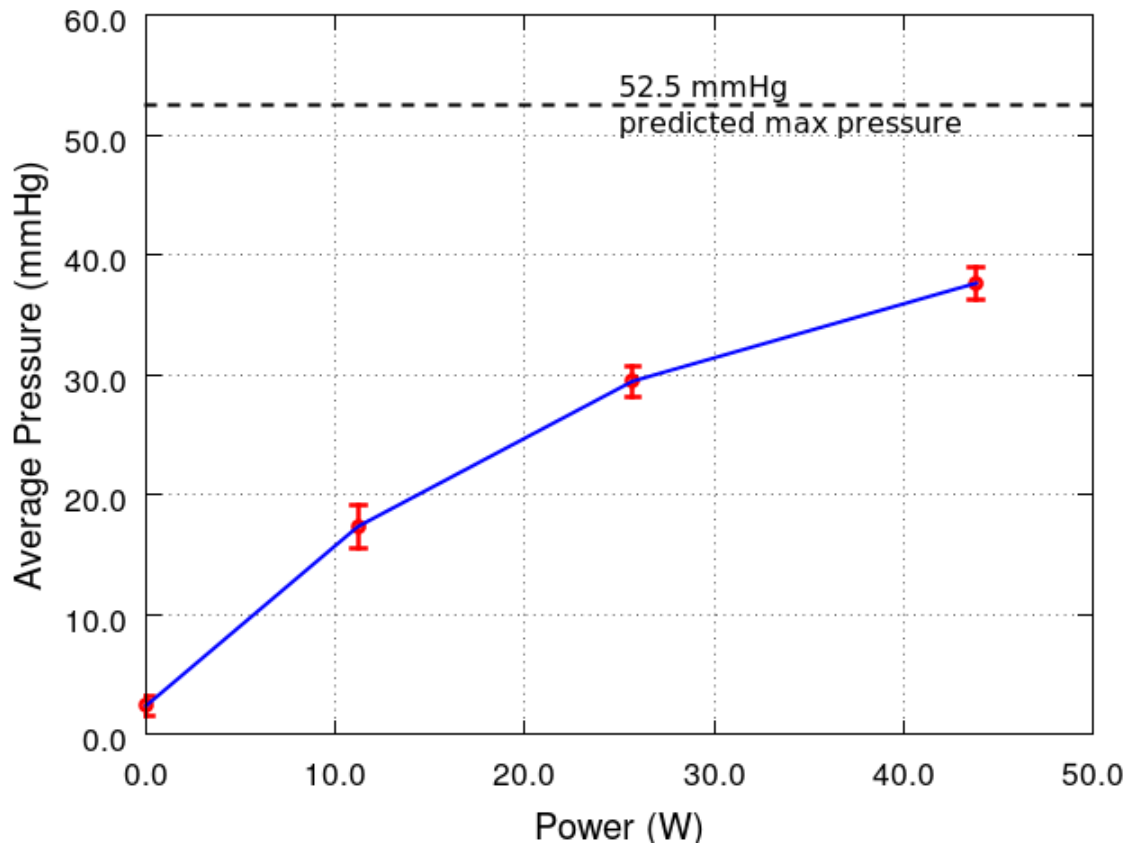


Figure 31: Depicts the average pressure output (mmHg) from all 5 samples of the average of the last 60 seconds of each power input (W). Standard deviation of pressure output is also depicted. The horizontal line represents the predicted maximum pressure output of 52.5 mmHg.

4.7 Discussion

The SMA garment pressure output increased with power input, however some variation in spatial distribution occurred, consistent with the unequal circumferential distribution observed in previous SMA compression garment tests (Holschuh and Newman, 2016).

Non-uniform pressure distributions can be caused by a variety of sources: the contraction force is localized (laterally on either side of the torso), causing adjacent areas to be more highly stretched than far-away regions; the interface between layers is not free of

frictional drag, causing additional unequal stretching of the garment materials; and the garment is heterogeneous in terms of its construction (with varying surface finishes and localized hard/soft regions), causing localized pressure “hot-spots” and voids. These features can be clearly seen in Figure 28: there are points of high pressure corresponding to the SMA actuators themselves and the boning structures in the garment, and there are also visible voids to either side of the SMA actuator. This is likely formed because the passive textile is held away from the form by the insulative layer below the SMA springs, and the boundary of the insulative layer creates a local discontinuity in fabric conformance to the underlying surface. Adding padding or fill in this area to translate force to the body might produce a more even distribution of pressure. Finally, across the front torso (the middle of the pressure map) there is also a slight variation in pressure distribution. This is likely caused by changes in the radius of curvature of the mannequin form, which would create varying pressures for a fixed circumferential tension.

A more even distribution is in theory preferable (Grandin, 1992), however in practice the effect of pressure distribution is unknown. The design of many existing products does not permit even pressure on all areas of the body. Weighted vests, for example, distribute force mainly over the shoulder area. A benefit of garment-integrated SMA actuators is the ability to adjust pressure location and intensity unobtrusively without doffing the garment, which could help to provide dynamic and adjustable DTP therapy treatments. This is especially true if actuation regions in the garment are designed to be independent circuits, enabling localized (or sequenced) dynamic compression profiles.

The garment produced 71.6% of maximum predicted pressure. This discrepancy is likely attributable to one (or more) violations of the underlying assumptions of the pressure production model: the mannequin form was not perfectly cylindrical; the SMA actuator output may not have been maximized (i.e., the actuators were not fully transformed even at 43.8 W); the garment was heterogeneous in construction (which as previously discussed, caused localized distortions in the pressure field); and the garment was not frictionless.

When evaluating the SMA-CG, we see that the garment meets or is capable of meeting (in a future implementation) most variables proposed in the framework. The SMA-CG design is fundamentally different from the commercial products in that is compression is created from an active alloy. The SMA-CG is able to provide controllable and repeatable, dynamic compression, while still maintaining an unobtrusive (without inflating) form factor because of its actuators. SMA's have also been shown to be able to be remotely controlled using Bluetooth LE (Duvall, Dunne, Schleif, & Holschuh, 2016)). This is an improvement, according to the framework, to commercial products (non-wearable options, weighted vests, negative ease stretch, and pneumatic). The broad range and controllable capabilities of the SMA-CG could be used to determine optimal values for key treatment pressure variable unknowns. The SMA-CG is capable of more than currently available products. However, it is not without its limitations. There are several variables that require further investigation.

One of these variables is the thermal comfort of the garment. The SMAs are activated through resistive heating, so the garment generates heat when activated. This

can be problematic by causing user discomfort and even compromising user safety if not managed. The initial prototype developed for this study was tested to its limit, which caused it to overheat, melting and singeing the fabric around the SMAs. This is one reason why the SMA-CG was not tested with the same methods as the commercial products and why there is no image of the garment. The textiles used to attach the SMAs and those in contact with the actuators were poorly chosen. Future iterations of SMA-CGs developed in the University of Minnesota Wearable Technology Lab for a different application utilized more appropriate materials when interfacing with the actuators. These included Teflon and fiberglass in areas touching the SMAs. The actuators must be, and can be, insulated from the wearer and environment. Heat should be managed and the clo value (a unit of thermal insulation) of the SMA-CG must be reduced in order to provide user comfort. This can be done through insulating the actuators and potentially other methods including using liquid cooling garments to regulate the wearer's body temperature (Watkins & Dunne, 2015). Additionally, the SMAs actuation temperature could be lowered by adjusting the temperature at which the actuators are annealed and by choosing alternative raw materials (alloys) that actuate at lower temperatures.

Beyond thermal comfort, there are several other requirements that were not met due to limited available time and other factors and require future investigation. These include integrated garment sensing, additional compression locations, and the form factor of the garment which encompasses the tactile comfort of the garment and future fit adjustability.

First, the SMA-CG does not have integrated sensing and monitoring capabilities. in

order to determine the effectiveness of the system and to create an autonomous system.

This could be done by measuring the pressure output of the garment, although there are limitations to measuring pressure on the body, and by measuring anxiety and arousal level. This feature could be integrated using skin conductance or heart rate variability (Chen, Yang, Chi, & Chen, 2013). It can be difficult to integrate sensors into a garment, where the wearer is moving and may not have constant garment-body contact. If a physiological anxiety sensor is successfully integrated into the garment system, it could be paired with the actuation capabilities of the garment to create an autonomous system that responds when needed. This could help to measure the effectiveness of a treatment and to detect a need for compression. An autonomous system could also help to mitigate the problem of misuse when experts are not present. The garment could continuously measure a need and alleviate or adjust pressure so the wearer does not become desensitized.

Second, the SMA-CG's compression was limited to the torso of the mannequin. The torso was chosen because the other commercially available products applied compression to the torso. However, after the qualitative investigation with experts and the evaluation of commercial products, it becomes evident that there are many possible locations for compression and that these locations vary per available treatment. Some suggested locations include, the head, shoulders, back, legs, arms, hands, feet and as much of the body as possible (investigation with experts). An evaluation of the pressure sensitivity over the body in relation to DTP therapies and their effectiveness should be conducted in order to determine optimal compression locations. Physiology experts

should be consulted in order to cross reference treatment strategies against what is known about tissue physiology with respect to pressure and perception. Additionally, vital organs, including located in the chest and belly region should potentially have reduced compression magnitudes in order to prevent any potential harm to the wearer (Watkins & Sparling, 2014). This requires further investigation, but indicates that the torso area may not be the best location for compression therapy. Further, the SMA-CG provides compression by using circumferential squeezing. This is easier to achieve by creating compression around a limb or other body part. Areas such as the shoulders may be more difficult to compress with SMAs, but could be achieved. Finally, the SMA-CGs are capable of compressing multiple areas of the body in programmable order. This is not possible with current products, so could open the door to future treatments. For instance, a massage type feature could be integrated to slowly apply compression up the wearer's arm, which is currently a treatment done by hand by OTs (CSLL OTs). The compression location for DTP and the new options SMA-CGs could provide should be investigated.

Finally, the form factor of the garment can be improved. This includes adjusting the neckline so it sits further away from the wearer's neck (Patricia Orme), reducing seams and choosing materials that are comfortable for the wearer (Haar, 1998). Additionally, a future iteration of the garment should accommodate size adjustability in order to fit a larger population and to accommodate an individual that is growing.

The SMA-CG was built as a prototype, so the cost of the garment is unknown.

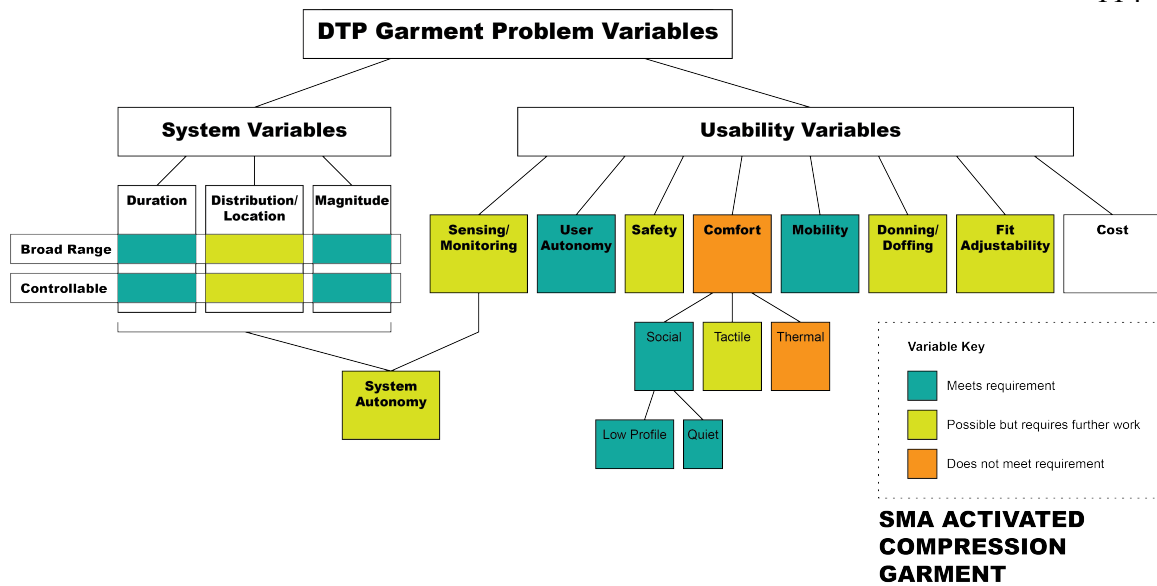


Figure 32: An evaluation of the SMA-CG using the problem variable framework.

In conclusion, the SMA-CG presents a viable alternative to commercial DTP products with controllable dynamic capabilities that have not been possible up until this point. This technology has exciting potential to provide future treatments that are not yet possible. Additionally, the garments could be used to quantify and study the many pressure treatment unknowns in the DTP literature (Morrison, 2007). Finally, SMA-CG Sensor integration could create an autonomous system. This could help to solve the fear of at home and classroom misuse (CSLL and UMN OTs) by providing a system that can self-adjust according to the sensed need and by providing programmable treatments that do not desensitize the wearer.

CHAPTER 5. CONCLUSIONS AND IMPLICATIONS

5.1 Summary

In the first chapter of this thesis, SPD is identified as a widespread (affecting 5%-16% or

children (Ahn et al., 2004; Ben-Sasson et al., 2009)) problem with the central nervous system that leads to numerous difficulties, including anxiety and challenges performing everyday tasks (About SPD, 2017). Current products are not meeting users' needs of autonomous, tunable, and unobtrusive dynamic compression. Additionally, there are gaps in understanding for the optimal metrics for DTP treatment. It becomes clear that requirements should be developed and a more ideal DTP therapy garment developed, these encompass the two research objectives of this thesis. The garment that is developed will be able to improve the lives of those with SPD and also can be leveraged as a tool to further understand optimal treatment parameters for this disorder.

In the second chapter of this thesis, the literature review, theories surrounding SPD are identified and shown to be evolving. Compression therapy is identified as one form of treatment for SPD that increases activity in the parasympathetic division of the ANS, and decreases activity in sympathetic nervous system (Chen et al., 2011). This promotes the production of neurotransmitters (serotonin and dopamine) that can calm the CNS (Morrison, 2007). Through a review of studies using DTP as a treatment we see that there are a wide array of methodologies, including the use of different wearable and non-wearable DTP products. The optimal magnitude, type (constant or changing), location, and duration of applied pressure for DTP treatment are unknown. Additionally, individuals with SPD have changing needs that may require a broad range of capabilities for each of these variables. Wearer autonomy, desensitization to pressure, integrated garment sensing, and functional and comfort requirements may also be important variables, but more work must be done to create a clearer set of requirements. Through a

review of current products, limitations are identified. Stretch garments are difficult to don and doff and can only provide static compression. Weighted vests must be removed or have weights adjusted in order to modify applied pressure. Pneumatic garments require a pump and inflate when pressure is applied or adjusted, which can be obtrusive. SMA-CGs are identified as a dynamic, controllable, and form fitting alternative to current DTP options.

A qualitative and quantitative exploration are conducted in order to further understand the current state of DTP compression therapy and build a set of requirements for a DTP therapy garment. Through the qualitative exploration with OTs and other experts, pressure location, magnitude, type, and duration, metric unknowns, social aspects, comfort, autonomy, feedback loop, emerge as important variables. Optimal treatment parameters, including location, magnitude, type, and duration of pressure, are not known and further research should be done. Through the quantitative evaluation of current DTP products, a weighted vest, a pneumatic garment, and a negative ease stretch garment, it becomes clear that protocol and distribution of pressure vary between currently available options. A problem variable framework is proposed, which encompasses system and usability variables and their requirements for an improved DTP therapy garment, see Figure 19.

The fourth chapter covers the development and evaluation of an active garment, incorporating SMAs (SMA-CG), built to meet the requirements identified in Chapter 3. The vest prototype integrates 16 SMA spring actuators (1.25 mm diameter, spring index = 3) that constrict when heated, producing large forces and displacements that can be

controlled via an applied current. When power is applied (up to 43.8 W), the prototype vest generates increasing magnitudes of pressure (up to 37.6 mmHg, spatially averaged across the front of the torso) on a representative child-sized form. Average pressure generated was measured up to 71.6% of the predicted maximum pressure, and spatial pressure non-uniformities were observed that can be traced to specific garment architectural features. The garment meets the requirements of repeatable dynamic compression in an unobtrusive form factor. Requirements, including integrated sensor feedback, fit adjustability, user comfort (thermal), and additional compression locations should be met in future garment iterations.

5.2 Overall Conclusions

There are many unknowns when it comes to the optimal treatment parameters for SPD (Morrison, 2007). Additionally, providing treatment is often a very individualistic and customized process (Olson & Moulton, 2004; OTs). Creating a garment that is capable of dynamic and controllable compression could help to better meet the needs of those with sensory processing difficulties. The garment build for this thesis can also be used as a tool to determine the unknowns for optimal DTP treatments. It could also provide customizable options that can meet the diverse needs of people with SPD so that they can function and fully live their lives.

The problem variable framework proposed in this thesis (chapter 3) identifies the important variables for DTP therapy. Many of the variables requirements are not clear (e.g. pressure duration, location and magnitude), so a broad range of capabilities is required until optimal parameters are determined. Current products (non-wearables,

weighted, stretch and pneumatic garments) are found to not meet different system and usability requirements. Dynamic capabilities are found to be integral to optimal DTP therapy. This variable framework should be developed so that specific requirements for all variables are determined. The importance of each variable should also be evaluated. Finally, the framework can be used to guide future DTP garment development.

Active DTP garments incorporating SMA actuators present a viable alternative to existing DTP therapy garments, with exciting potential for both precise control of applied pressures and the ability to present dynamic pressure localization and intensity regimens. The SMA vest approach is an unobtrusive, dynamic option, which has the direct capability to be activated remotely via Bluetooth LE (Duvall, Dunne, Schleif, & Holschuh, 2016)). This allows the wearer to self-adjust and overcome desensitization from pressure, as well as allowing OTs or caregivers to prescribe a dynamic sensory diet that can be actuated unobtrusively and remotely (enabling a new paradigm of tele-rehabilitation or treatment).

Additionally, the SMA vest has significant potential as a research tool to evaluate and standardize DTP treatments. This could be used to more fully investigate the effectiveness of DTP therapy, which is currently not well understood (due in no small part to the limitations of current actuation technologies) (Morrison, 2007). Pressure distribution over the body surface and its impact on treatment success are high-potential areas for future exploration, in parallel with evaluation of the effectiveness of dynamic treatments with human subjects.

Finally, as compression therapy is used to treat a variety of medical conditions

beyond SPD (e.g., diabetes, lymphedema, burns, etc.), the technology developed for this thesis has widespread clinical potential that warrants further investigation.

5.3 Limitations

There are several limitations to this work, many of which are due to limited time. These limitations include, restricted expert input, no human subjects testing, unmet problem variable requirements, pressure measurement difficulties, including the sensor and the test mannequin.

Regarding the study, the input from OTs was restricted to only a few experts, and input was not received from individuals suffering from SPD. The garment's effectiveness was not tested with human subjects. These limitations were due to time restrictions.

Additionally, there are several garment requirements that were not incorporated due to limited time and feasibility. These include garment size adjustability, alternative pressure locations, and thermal comfort.

Further, there were several limitations to the pressure measurement system. Pressure measurements were reported in raw values due to difficulties in calibration at low pressures with available equipment. We do not know how the SMA-CG is performing relative to the commercial garments because of this limitation. However, the SMA-CG can provide a broad range, comparable to compression products for other therapeutic purposes (Teng & Chou, 2006; Brennan & Miller, 1998), that is would most likely encompass the range of commercial DTP products. The measurement of normal forces on the body surface is a complex challenge, for which there is no ideally-suited method. In the thesis presented here, the best-fit technology available was used, but

limitations to the method prevented measurement of pressures applied to the dorsal surface of the mannequin. To effectively measure normal forces over the full topography of the body, it would be necessary to achieve either a more fully 3-D conformable force measurement device or a custom-fit force measurement platform.

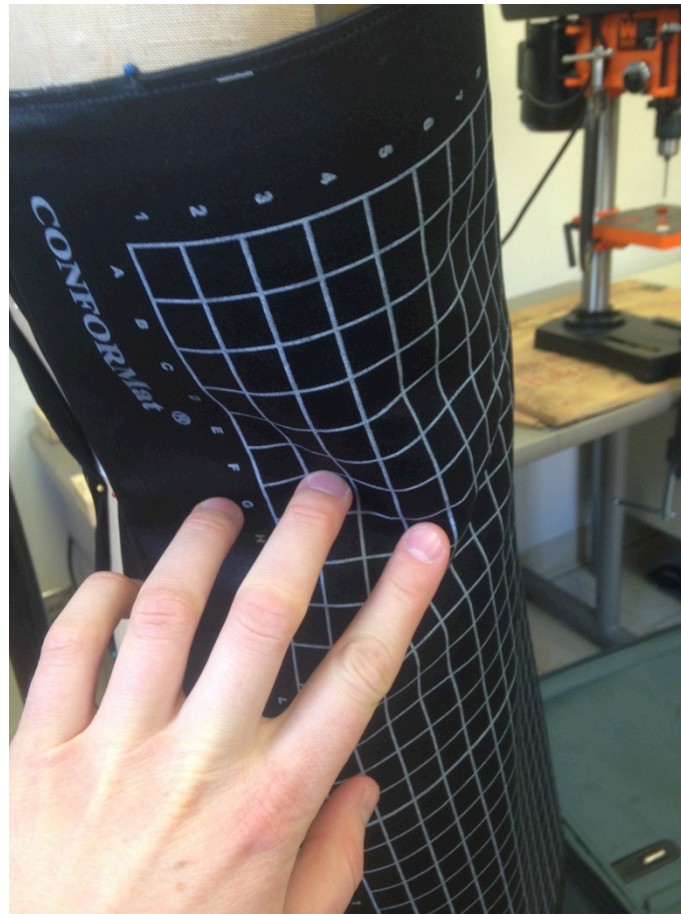


Figure 33: The 2D Tekscan sensor can create false pressure readings from bending when placed on the 3D form (size 3T mannequin). Additionally, the sensor mat can alter the fit of a garment due to bulk.

Finally, the experimental protocol implemented here relies on a rigid mannequin in place of a human body. The mannequin surface does not approximate the mechanics of the body, and therefore there are likely to be inconsistencies, particularly in the distribution of force over the body surface. These factors are also likely to change

between individuals, as individual anthropometry and body topography is highly variable.

5.4 Future work

5.4.1 SMA-CGs

There are several different future work opportunities for the SMA-CGs. These include heat management for better thermal comfort, sizing and fit adjustments, improve form factor and usability,

First, heat management should be controlled, reducing the clo value, in order to provide thermal comfort for the wearer. The SMAs are actuated using heat, so the garment generates heat when compressing. The initial prototype for this thesis was melted where it was in contact with the fully heated SMAs due to poor material choices. Mitigating the heat of the garment can be done in several different ways. First the materials in contact with the actuators should be chosen carefully for their heat resistive properties (e.g. Teflon and fiberglass). The SMAs should be thermally insulated from the wearer and the environment. Additionally, the SMA actuation temperature can be reduced in order to reduce the clo value of the garment system. This can be done by annealing the SMAs at lower temperatures and by choosing alternative alloys. Finally, the garment system could also be cooled using a liquid cooling garment (Watkins & Dunne, 2015) beneath the SMA-CG. Thermal comfort and safety is extremely important. Because of the fundamental design of the SMA-CG, heat is generated through actuation, however this can be controlled and managed.

Beyond heat management, there are several other alterations that should be made for future SMA-CG iterations. The garment should be constructed in sizes appropriate for human subjects testing. The garment neckline should be reduced to give the wearer more room. Washability should be taken into account (e.g. a removable muscle layer should be added in order to facilitate easy washability). The SMA actuators design should be optimized in order to reduce power usage and heat. An analog electronics system should be developed to accommodate controllable and variable pressure. Alternative pressure locations should be explored leveraging physiology experts and an evaluation of pressure sensitivity over the body. Finally, sensors should be integrated into the garment system in order to measure anxiety level. Both skin conductance or electrodermal activity (EDA) and heart rate variability (HRV) have been shown to indicate anxiety and arousal level. Chen et al. found statistically significant results when using DTP for anxiety reduction using these measures (Chen, Yang, Chi, & Chen, 2013). These measures of anxiety have been shown to be positively correlated to anxiety reduction (Chen, Yang, Chi, & Chen, 2013), however this is for a healthy population, and this measurement tool should be evaluated for those with SPD. Sensing capabilities, in conjunction with garment actuation, can be used to build an autonomous system. This can be used to provide customized treatments and help to reduce at home and classroom misuse by reducing human error.

5.4.2 Pressure Measurement

There are several future work opportunities regarding on-body pressure measurement. These encompass both an improved sensor form factor as well as improved pressure sensor calibration methods.

Current sensor form factor are limitations, see figure 33. The sensor itself creates bulk and does not conform well to a 3D human form. The pressure data collected in this thesis was limited to the abdomen and one point measurement on the shoulder. Future work should aim to more extensively measure the normal force generated by DTP products, including spatial distribution on the shoulders and back. Pressure measurement tools should be developed in order to meet the need for accurate on-body pressure measurement. This could be done in several different ways. The sensors could be directly integrated into the garment. However, this would make calibration or zeroing of the sensor difficult. The sensor can be zeroed by placing it on the wearer or mannequin and measuring the pressure output without the garment applied, then spatially subtracting this from the data. An alternative would be to create a custom sensor garment for the body part (if tested on a human), or an entire instrumented mannequin that can measure garment pressure. Current pressure measurement tools are not built for on body measurement. Future work should aim to meet the need for a body-conformable pressure measurement tool.

Beyond the 3-D form of the sensor, methods for accurate calibration of both FSR force sensing and Tekscan pressure map sensing should be investigated. Pressure calibration on a 3D form or body at low pressures has been acknowledged to be difficult

(Macintyre, 2011). The pressure data collected for this thesis was left uncalibrated due to difficulty finding adequately accurate calibration methods. The CONFORMat sensor (Tekscan Inc.) used for this thesis, is intended for measuring seated pressure, not pressure generated from compression garments. This sensor is able to map out an area using a grid of sensors and has a laser cut pattern to allow the sensor mat to conform to an irregular surface. This sensor seems ideal for on body pressure measurement, however the suggested calibration method (as well as other limitations) are not well suited to on body applications. First, the calibration method should closely mimic the data collection set-up. This means that the materials in contact with the sensor should mimic the materials that will be in contact with the sensor during data collection (the body on one side and the garment on the other side). Additionally, the sensor is curved when on the body, so it should be curved when calibrated. Finally, the calibration pressure should also fall within the range of expected data pressures. The calibration method outlined by the manufacturer, uses a vacuum bag to apply known pressures to the sensor. For the suggested calibration, the sensor is lying flat and the vacuum bag acts as a rigid surface, and the recommended pressures used to calibrate are much higher than the expected data values. An alternative calibration method should be investigated.

Macintyre conducted a study to develop an on-body pressure measurement calibration method for the I-Scan sensor (Macintyre, 2011). Her study tested various one-point calibrations at different applied pressures. The test set up aimed to closely mimic the data collection set-up, by wrapping the sensor around a cylinder the size of a limb (what was being measured). Foam was attached to the cylinder in order to closely mimic

the human limb/tissue, the sensor was taped to this, and an inflatable blood pressure cuff was wrapped around the sensor in order to apply the calibration pressure. Macintyre was able to find a calibration able to provide within $\pm 2\text{mmHg}$ of accuracy (Macintyre, 2011). A similar study should be conducted for the CONFORMat sensor. The CONFORMat is larger than the I-Scan sensor used in Macintyre's study, so a blood pressure cuff may not be an appropriate method for applying the calibration pressure. Additionally, the CONFORMat was chosen in order to measure pressure applied to the torso as well as the limbs. A possible option for applying pressure for calibration could be to attach the sensor to a mannequin and then use an inflatable garment to apply the calibration pressure. These methods should be investigated and tested.

5.4.3 Human Subjects Testing

Once the new SMA-CGs are developed they should be tested with human subjects, first with a healthy population followed by the target population (those with SPD). This process should be guided with the expertise of OTs. By receiving user feedback from participants, the SMA-CG can be improved in order to provide a more effective treatment. Further investigation through interviews with individuals with SPD and user testing may lead to more problem variables and requirements. The variable framework should be tested, both for its accuracy and for the level of importance of each variable. This framework should inform future garment designs. Once the design is optimized, the SMA-CG's optimal pressure metrics, including pressure magnitude, duration, location, and type (changing or constant) should be investigated and quantified

if possible. Participant selection criteria, data collection methods, and expected outcomes should be clearly delineated with the help of OTs.

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